# Health Care Appropriations Committee

**Tuesday, April 11, 2006**
**9:30 a.m. – 12:00 p.m.**
**Morris Hall (17 HOB)**

## Meeting Packet (1 of 3)

**Allan Bense**
**Speaker**

**Aaron Bean**
**Chair**

# Florida House of Representatives

Fiscal Council
Health Care Appropriations Committee

**Allan Bense**
Speaker

**Aaron Bean**
Chair

Agenda
Tuesday, April 11, 2006
Morris Hall (17 HOB)
9:30 a.m. – 12:00 p.m.

I. Call to Order

II. Roll Call

III. Opening Remarks

IV. Consideration of the following bill(s):
- HB 13 CS Department of Elderly Affairs by Robaina
- HB 371 CS Cancer Drug Donation Program by Harrell
- HB 577 Medicaid Comprehensive Geriatric Fall Prevention Program by Garcia
- HB 595 CS Community Behavioral Health Agencies by Cannon
- HB 645 CS Nursing Home Facilities by Gelber
- HB 715 CS Trauma Services by Grimsley
- HB 819 CS Radiologist Assistants by Grant
- HB 1033 CS Child Abuse by Vana
- HB 1093 CS Physicians by Altman
- HB 1247 CS Developmental Disabilities by Kravitz
- HB 1365 CS Florida KidCare Program by Davis, M.
- HB 1417 CS Hospices by Sansom
- HB 1449 CS Brain Tumor Research by Gannon
- HB 1503 CS Persons with Disabilities by Galvano
- HB 1557 CS Wekiva Onsite Sewage Treatment and Disposal System Compliance Grant Program by Brummer
- HB 7065 CS Clandestine Laboratory Contamination by Health Care Regulation Committee
- HB 7141 Licensure of Health Care Providers by Health Care Regulation Committee

V. Closing Remarks

VI. Adjournment

# Committee Meeting Notice

## HOUSE OF REPRESENTATIVES

**Speaker Allan G. Bense**

## Health Care Appropriations Committee

**Start Date and Time:** Tuesday, April 11, 2006 09:30 am

**End Date and Time:** Tuesday, April 11, 2006 12:00 pm

**Location:** Morris Hall (17 HOB)
**Duration:** 2.50 hrs

**Consideration of the following bill(s):**

HB 13 CS Department of Elderly Affairs by Robaina
HB 371 CS Cancer Drug Donation Program by Harrell
HB 577 Medicaid Comprehensive Geriatric Fall Prevention Program by Garcia
HB 595 CS Community Behavioral Health Agencies by Cannon
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HB 7065 CS Clandestine Laboratory Contamination by Health Care Regulation Committee
HB 7141 Licensure of Health Care Providers by Health Care Regulation Committee

**NOTICE FINALIZED on 04/07/2006 16:15 by RYA**

## HOUSE OF REPRESENTATIVES STAFF ANALYSIS

**BILL #:** HB 13 CS Department of Elderly Affairs
**SPONSOR(S):** Robaina and others
**TIED BILLS:** **IDEN./SIM. BILLS:** SB 1330

| REFERENCE | ACTION | ANALYST | STAFF DIRECTOR |
|---|---|---|---|
| 1) Governmental Operations Committee | 6 Y, 0 N, w/CS | Brown | Williamson |
| 2) Elder & Long-Term Care Committee | 8 Y, 0 N | DePalma | Walsh |
| 3) Health Care Appropriations Committee | | Massengale | Massengale |
| 4) State Administration Council | | | |
| 5) | | | |

## SUMMARY ANALYSIS

The bill specifies that if the Department of Elderly Affairs takes any intermediate measures against an area agency on aging for failing to provide certain contract services, and if the area agency on aging fails to improve service delivery after at least 90 days, the department may terminate the relevant contract(s) and re-contract for the service or provide the service directly to the affected population. The bill requires an evaluation before terminating an area agency.

Subsequent contracts must be made competitively, in accordance with chapter 287, F.S. The department may temporarily provide the service, but the competitive procurement process must begin within 180 days.

The department has said there is no fiscal impact associated with the bill.

The effective date of the bill is July 1, 2006.

## FULL ANALYSIS

## I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

**Safeguard individual liberty** –The bill provides for more immediate termination and re-bidding of poorly-operating contracts for programs delivering services to the elderly.

B. EFFECT OF PROPOSED CHANGES:

Current Situation

The Department of Elderly Affairs (hereinafter the department) assists and protects the state's elderly citizens "to the fullest extent."[1] One of the primary duties of the department is the delivery of federally-funded programs and services,[2] and the administration of "human services programs" for the elderly.[3] These programs and services are coordinated with area agencies on aging, groups organized at the regional level,[4] which in turn directly contract for particular services.[5]

The department is tasked with ensuring that each area agency on aging (hereinafter AAA or agency) "operates in a manner to ensure that the elderly of this state receive the best services possible."[6] The department monitors the AAAs to ensure that none of the following problems arise:[7]

- An intentional or negligent act of the agency has materially affected the health, welfare, or safety of clients, or substantially and negatively affected the operation of an aging services program.
- The agency lacks financial stability sufficient to meet contractual obligations or that contractual funds have been misappropriated.
- The agency has committed multiple or repeated violations of legal and regulatory requirements or department standards.
- The agency has failed to continue the provision or expansion of services after the declaration of a state of emergency.
- The agency has exceeded its authority or otherwise failed to adhere to the terms of its contract with the department or has exceeded its authority or otherwise failed to adhere to the provisions specifically provided by statute or rule adopted by the department.
- The agency has failed to properly determine client eligibility as defined by the department or efficiently manage program budgets.
- The agency has failed to implement and maintain a department-approved client grievance resolution procedure.

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[1] Section 430.02(1), F.S.
[2] Section 430.02(2), F.S.
[3] Section 430.03(1), F.S.
[4] The State of Florida is currently divided into 11 Planning and Service Areas, according to the *2005 Annual Report Summarizing DOEA's Monitoring Activities of Area Agencies on Aging* (hereinafter the *2005 Annual Report*).
[5] *2005 Annual Report,* p. 1
[6] Section 430.04(2), F.S.
[7] Section 430.04(2)(a) – (f), F.S.

In the event any of these problems occur, the department may rescind an AAAs official status or take intermediate measures including:[8]

- Corrective actions.
- Unannounced special monitoring.
- Temporary assumption of operations.
- Placement on probationary status.
- Moratorium on agency action.
- Financial penalties for non-performance.
- Other administrative action pursuant to chapter 120, F.S.

Proposed Changes

The bill modifies s. 430.04(2), F.S., to specify that administrative action pursuant to chapter 120, F.S., can be taken only after an evaluation.

The bill also provides that, in the event the Department takes any "intermediate measures" against an AAA for services not funded under the federal Older Americans Act,[9] and the AAA fails to improve service delivery after at least 90 days, the department may terminate the relevant contract(s) and re-contract for the service or provide the service directly to the affected population.

If the department elects to re-contract for the service previously provided by the AAA, the subsequent contract must be made competitively, in accordance with chapter 287, F.S.[10] The department may provide the affected service directly, for a limited time, but the competitive procurement process must begin within 180 days of the termination of the AAA.

In addition to these safeguards, any contracts made with a service provider by the AAA after July 1, 2006, must contain an assignment clause allowing the department or another designee to become the assignee of the contract, to ensure continuity of service.

C. SECTION DIRECTORY:

**Section 1.** Amends s. 430.04, F.S., requiring an evaluation before the department can take action against an area agency on aging; permitting the department to terminate contracts and provide for alternative methods of service delivery under certain circumstances; and requiring assignment clauses in future contracts between AAAs and service providers.

**Section 2.** Provides an effective date of July 1, 2006.

## II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   The bill does not create, modify, amend, or eliminate a state revenue source.

2. Expenditures:

   The bill does not create, modify, amend, or eliminate a state expenditure.

[8] Section 430.04(2), F.S.
[9] Services "not funded under the federal Older Americans Act" refers to services funded through the state's General Revenue Fund or the Tobacco Settlement Trust Fund.
[10] Generally speaking, chapter 287, F.S., mandates competitive open bidding for all commodities and services purchased by agencies.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

The bill does not create, modify, amend, or eliminate a local revenue source.

2. Expenditures:

The bill does not create, modify, amend, or eliminate a local expenditure.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

## III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not appear to require counties or municipalities to take an action requiring the expenditure of funds, reduce the authority that counties or municipalities have to raise revenue in the aggregate, nor reduce the percentage of state tax shared with counties or municipalities.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The department already seems to possess authority under current state law to discipline and sanction AAAs violating federal or state statutes, rules and policies. Under s. 430.04(2), F.S., in addition to the range of "intermediate measures" that the department may pursue against an AAA, the department is authorized to rescind the designation of an area agency on aging in certain situations. Similarly, Rule 58A-1.006(6), F.A.C., provides that the department shall withhold distribution of a portion of the contract funds designated for an AAA in proportion to the amount of services not furnished by the AAA.

## IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

On March 29, 2006, the Governmental Operations Committee adopted a proposed committee substitute and reported the bill favorably with committee substitute. The bill completely overhauled chapter 430, F.S. The committee substitute limited the changes to the following:

- The department may take intermediate measures against an AAA after an evaluation.
- The department may terminate a contract with an AAA under certain circumstances.
- Re-procurement of services must be made in accordance with chapter 287, F.S., and must begin within 180 days of termination.
- Assignment clauses are required in future contracts between AAAs and service providers.

CHAMBER ACTION

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The Governmental Operations Committee recommends the following:

**Council/Committee Substitute**

Remove the entire bill and insert:

A bill to be entitled

An act relating to the Department of Elderly Affairs; amending s. 430.04, F.S.; requiring the Department of Elderly Affairs to conduct an evaluation prior to rescinding designation of or taking certain measures against an area agency on aging; providing circumstances under which the department may terminate an area agency on aging contract; authorizing the department to contract with certain entities to provide programs and services under certain circumstances; requiring the department to initiate a competitive procurement process to replace an area agency on aging within a specified time period; providing for certain contracts and agreements to be assignable to the department and, subsequently, to an entity selected to replace the area agency on aging; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Subsection (2) of section 430.04, Florida Statutes, is amended, subsections (3) through (16) are renumbered as subsections (4) through (17), respectively, and a new subsection (3) is added to that section, to read:

430.04 Duties and responsibilities of the Department of Elderly Affairs.--The Department of Elderly Affairs shall:

(2) Be responsible for ensuring that each area agency on aging operates in a manner to ensure that the elderly of this state receive the best services possible. The department shall rescind designation of an area agency on aging or take intermediate measures against the agency, including corrective action, unannounced special monitoring, temporary assumption of operation of one or more programs by the department, placement on probationary status, imposing a moratorium on agency action, imposing financial penalties for nonperformance, or other administrative action pursuant to chapter 120, if, after an evaluation, the department finds that:

(a) An intentional or negligent act of the agency has materially affected the health, welfare, or safety of clients, or substantially and negatively affected the operation of an aging services program;~~.~~

(b) The agency lacks financial stability sufficient to meet contractual obligations or that contractual funds have been misappropriated;~~.~~

(c) The agency has committed multiple or repeated violations of legal and regulatory requirements or department standards;~~.~~

(d) The agency has failed to continue the provision or expansion of services after the declaration of a state of emergency;~~.~~

(e) The agency has exceeded its authority or otherwise failed to adhere to the terms of its contract with the department or has exceeded its authority or otherwise failed to adhere to the provisions specifically provided by statute or rule adopted by the department;~~.~~

(f) The agency has failed to properly determine client eligibility as defined by the department or efficiently manage program budgets; or~~.~~

(g) The agency has failed to implement and maintain a department-approved client grievance resolution procedure.

(3) If the department takes an intermediate measure against an area agency on aging as provided in subsection (2) and the department determines, at least 90 days after such measure is taken, that the agency has failed to effectively plan, fund, or administer contracts for programs and services not funded by the federal Older Americans Act, the department may terminate an agency's contract for such programs or services. Notwithstanding any law to the contrary, in the event of the termination of a contract with an agency, the department shall contract, in accordance with chapter 287, with an entity to plan, fund, and administer the programs and services previously under contract in the affected planning and service area. The department may directly provide the affected program or service for a limited period of time but shall initiate a competitive procurement process to replace the agency within 180

days after the termination of the agency's contract. Any contract or referral agreement effective on or after July 1, 2006, between an area agency on aging and a lead agency or service provider must be assignable to the department and subsequently to an entity competitively selected under this subsection.

Section 2. This act shall take effect July 1, 2006.

## HOUSE OF REPRESENTATIVES STAFF ANALYSIS

**BILL #:** HB 371 CS Cancer Drug Donation Program
**SPONSOR(S):** Harrell
**TIED BILLS:** **IDEN./SIM. BILLS:** SB 1310

| REFERENCE | ACTION | ANALYST | STAFF DIRECTOR |
|---|---|---|---|
| 1) Health Care General Committee | 10 Y, 0 N, w/CS | Brown-Barrios | Brown-Barrios |
| 2) Judiciary Committee | 13 Y, 0 N, w/CS | Hogge | Hogge |
| 3) Health Care Appropriations Committee | | Money | Massengale |
| 4) Health & Families Council | | | |
| 5) | | | |

## SUMMARY ANALYSIS

House Bill 371 CS creates the Cancer Drug Donation Program Act under s. 381.94, F. S. The bill requires the Department of Health (DOH) to establish and maintain a cancer drug and supplies donation program under which a donor may donate cancer drugs or supplies needed to administer cancer drugs for use by an individual who meets eligibility criteria specified by DOH in rule. The department is authorized to adopt rules for the implementation of the program.

Donations may be made only at a hospital pharmacy that elects or volunteers to participate in the program. A dispensing pharmacy may charge a handling fee sufficient to cover the cost of preparation and dispensing of cancer drugs or supplies under the program. Under the bill, a cancer drug may only be accepted or dispensed under the program if such drug is in its original, unopened, sealed container or packaging. A cancer drug cannot be accepted or dispensed under the program if the drug bears an expiration date that is less than six months after the date the drug was donated or if the drug appears to have been tampered with or mislabeled.

A person who is eligible to receive cancer drugs or supplies under the state Medicaid program or under any other prescription drug program funded in whole or in part by the state, or by any other prescription drug program funded in whole or in part by the federal government, or by any other prescription drug program offered by a third-party insurer, is ineligible to participate in the program, unless benefits have been exhausted, or a certain cancer drug or cancer supply is not covered by their prescription drug program.

The bill requires DOH to establish and maintain a participant facility (i.e., hospital pharmacy) registry for the program. The registry must include the name, address, and telephone number of the facility.

The bill provides immunity from civil and criminal liability for donors and program participants and renders pharmaceutical manufacturers not liable in certain circumstances.

The bill provides an appropriation of $65,308 from the General Revenue Fund for FY 2006-07.

The effective date of this bill is July 1, 2006.

## FULL ANALYSIS

## I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

**Provide limited government**—The bill creates an additional responsibility for the Department of Health and authorizes the development of additional rules.

**Ensure lower taxes**—The bill permits a participant facility dispensing cancer drugs or supplies under the proposed donation program, to charge a handling fee sufficient to cover the cost of preparation and dispensing of cancer drugs or supplies.

**Promote personal responsibility**—The bill allows individuals to contribute cancer drugs on a voluntary basis.

**Empower families**—The bill provides opportunities for certain families with limited resources to pursue less costly cancer treatments.

B. EFFECT OF PROPOSED CHANGES:

House Bill 371 CS creates the Cancer Drug Donation Program Act under s. 381.94, F. S. The bill requires DOH to establish and maintain a cancer drug and supplies donation program under which a donor defined as a patient or patient representative, physician, health care facility, nursing home, hospice, or hospital pharmacy may donate cancer drugs provided that it has been maintained within a closed-drug delivery system[1] or supplies needed to administer cancer drugs for use by an individual who meets eligibility criteria specified by DOH in rule. Drug manufacturers, medical device manufacturers or suppliers, wholesalers of drugs or supplies may also donate cancer drugs or supplies to the program. The department is authorized to adopt rules for the implementation of the program.

Donations may be made only at a hospital pharmacy that elects or volunteers to participate in the program. A dispensing pharmacy may charge a handling fee sufficient to cover the cost of preparation and dispensing of cancer drugs or supplies under the program. Under the bill, a cancer drug may only be accepted or dispensed under the program if the drug is in its original, unopened, sealed container or packaging. A cancer drug cannot be accepted or dispensed under the program if it bears an expiration date that is less than six months after the date the drug was donated or if the drug appears to have been tampered with or mislabeled.

A person who is eligible to receive cancer drugs or supplies under the state Medicaid program or under any other prescription drug program funded in whole or in part by the state, or by any other prescription drug program funded in whole or in part by the federal government, or by any other prescription drug program offered by a third-party insurer, is ineligible to participate in the program, unless benefits have been exhausted, or a certain cancer drug or cancer supply is not covered by their prescription drug program.

The bill requires DOH to establish and maintain a participant facility (i.e., hospital pharmacy) registry for the program. The registry must include the name, address, and telephone number of the facility. The department must make the participant facility registry available on the department's website to any donor wishing to donate cancer drugs or supplies to the program. The department web site shall also contain links to cancer drug manufacturers that offer drug assistance programs or offer free medication.

Under the act, a donor of cancer drugs or supplies or a program participant who exercises reasonable care in donating, accepting, distributing, or dispensing cancer drugs or supplies under the program is immune from civil or criminal liability and from professional disciplinary action of any kind for any injury, death, or loss to person or property relating to activities of the program.

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[1] Defined in the bill as a system in which the actual control of the unit-dose medication package is maintained by a facility rather than by the individual patient.

In addition, a pharmaceutical manufacturer is not liable for any claim or injury arising from the transfer of any cancer drug under the program, including, but not limited to, liability for failure to transfer or communicate product or consumer information regarding the transferred drug, as well as the expiration date of the transferred drug.

Because the bill creates new law and allows the donation of cancer drugs or supplies currently prohibited by statute and regulations, the bill provides that if any conflict exists between the provisions contained in the newly created s. 381.94, F. S., and provisions in chapter 465, F. S.,[2] or chapter 499, F. S.,[3] the provisions contained in s. 381.94, F. S., shall control as to the operation of the Cancer Drug Donation Program Act.

The bill provides an appropriation of $65,308 from the General Revenue Fund for FY 2006-07 to DOH to administer the program.

BACKGROUND AND CURRENT SITUATION

Cancer is a general term for a group of diseases in which abnormal cells grow out of control. Cancer cells can invade nearby tissues and can spread through the bloodstream and lymphatic system to other parts of the body.[4] Cancer is the second leading cause of death in Florida and in the United States. In 2005, an estimated 570,000 Americans—or more than 1,500 people a day—were expected to die of cancer. Of these annual cancer deaths, 40,090 are expected in Florida. In addition, approximately 1.4 million new cases of cancer were expected to be diagnosed nationally. This figure includes an estimated 96,200 new cases that were likely to be diagnosed in Florida.[5]

| Estimated New Cases of Cancer – 2005 | | |
|---|---|---|
| **Types of Cancers** | **US** | **FL** |
| All Cancers | 1,372,910 | 96,200 |
| Breast (female) | 211,240 | 13,430 |
| Uterine Cervix | 10,370 | 730 |
| Colon & Rectum | 145,250 | 9,860 |
| Uterine Corpus | 40,880 | 2,520 |
| Leukemia | 34,810 | 2,620 |
| Lung & Bronchus | 172,570 | 13,130 |
| Melanoma of the skin | 59,580 | 4,600 |
| Non-Hodgkin Lymphoma | 56,390 | 3,470 |
| Prostate | 232,090 | 19,650 |
| Urinary Bladder | 63,210 | 4,890 |

The financial costs of cancer treatment are a burden to people diagnosed with cancer, their families, and society as a whole. Nationally, cancer treatment accounted for an estimated $72.1 billion in 2004 spending.[6] The cost of treating cancer varies greatly by the type of cancer an individual has been diagnosed to have.

[2] Regulation of pharmacies.
[3] Regulation of drug, cosmetic, and household products.
[4] National Cancer Institute – Dictionary of Cancer Terms.
[5] Source: Cancer Facts & Figure, American Cancer Society, 2005.
[6] 1963-1995: Brown ML, Lipscomb J, Snyder C. The burden of illness of cancer: economic cost and quality of life. Annual Review of Public Health 2001;22:91-113. : NIH Report to the U.S. Congress, 2005; National Health Care Expenditures Projections: 2003-2013

| Estimates of National Expenditures for Medical Treatment for the 15 Most Common Cancers[7] | | | | |
|---|---|---|---|---|
| | Percent of all new cancers (1998) | Expenditures (billions; in 2004 dollars) | Percent of all cancer treatment expenditures | Average Medicare first year cost (2004 dollars) |
| Lung | 12.7% | $9.6 | 13.3% | $24,700 |
| Breast | 15.9% | $8.1 | 11.2% | $11,000 |
| Colorectal | 10.7% | $8.4 | 11.7% | $24,200 |
| Prostate | 16.8% | $8.0 | 11.1% | $11,000 |
| Lymphoma | 4.6% | $4.6 | 6.3% | $21,500 |
| Head/Neck | 2.8% | $3.2 | 4.4% | $18,000 |
| Bladder | 4.4% | $2.9 | 4.0% | $12,300 |
| Leukemia | 2.4% | $2.6 | 3.7% | $18,000 |
| Ovary | 1.9% | $2.2 | 3.1% | $36,800 |
| Kidney | 2.6% | $1.9 | 2.7% | $25,300 |
| Endometrial | 2.9% | $1.8 | 2.5% | $16,200 |
| Cervix | 0.8% | $1.7 | 2.4% | $20,100 |
| Pancreas | 2.3% | $1.5 | 2.1% | $26,600 |
| Melanoma | 4.0% | $1.5 | 2.0% | $4,800 |
| Esophagus | 1.0% | $0.8 | 1.1% | $30,500 |
| All Other | 14.0% | $13.4 | 18.5% | $20,400 |

Lack of health insurance and other barriers to health care prevent many Americans from receiving optimal medical care. According to the 2003 national health survey data, there are approximately 2.9 million Floridians who lack health insurance.

Insurance Status of Floridians

| Source of Insurance for Floridians | | | | |
|---|---|---|---|---|
| Source of Insurance | FL Population | % | US Population | % |
| Employer | 7,956,640 | 48 | 156,270,570 | 54 |
| Individual | 990,350 | 6 | 13,593,990 | 5 |
| Medicaid | 2,007,000 | 12 | 38,352,430 | 13 |
| Medicare | 2,726,250 | 16 | 34,190,710 | 12 |
| Uninsured | 2,957,290 | 18 | 44,960,710 | 16 |
| Total | 16,637,520 | 100 | 287,368,410 | 100 |

(Source: Kaiser Foundation - Population Distribution by Insurance Status, state data 2002-03, U.S. 2003)

According to National Institute of Health (NIH) - Cancer Institute, there are 500 agents (i.e., drugs) that are being used in the treatment of patients with cancer or cancer-related conditions.[8] There are estimates that consumers leave unused approximately $1 billion worth of unused prescription drugs[9] per year.

Cancer drug donation or repository program

To address the issue of affordability of treatment and unused prescription medication to treat cancer, some states have established a cancer drug donation or repository program to accept unused, unopened, prescription drugs and medical supplies. Wisconsin,[10] Colorado[11] and Nebraska[12] are among the states that have passed cancer drug donation laws. Several other states are considering similar legislation.[13]

In general, the cancer donation programs being established in other states have similar characteristics. These characteristics include, but are not limited to:

[7] Cancer Trend Progress Report – 2005 Update, U.S. National Institute of Health – National Cancer Institute.
[8] NCI Drug Dictionary, NIH-National Institute of Health, 2005.
[9] "Old Pills Finding New Medicine Cabinets," NY Times, May 18, 2005. This reference is to all prescription drugs not just drugs to treat cancer.
[10] Section 255.056, Wisconsin Statutes.
[11] Section 25-35-101, Colorado Statute.
[12] Title 181 Chapter 6, Nebraska Statute.
[13] National Conference of State Legislatures, 2005 Summary of Prescription Drug State Legislation.

- A mechanism to accept unused, unopened, individually packaged prescription drugs and medical supplies from individuals and health care facilities and these would be redistributed to uninsured and under-insured cancer patients.
- Preference being given to the uninsured for access to donated drugs and supplies.
- Donated drugs being distributed only when prescribed by a doctor and dispensed by a pharmacist.
- Donated drugs and supplies being in their original, unopened, sealed and tamper-evident packaging.
- Health facilities being able to charge a handling fee for dispensing donated cancer drugs, but not reselling donated drugs.
- Having a central registry operated by a state agency to track participating facilities.

Relevant Statutory Provisions

*Section 465.016, Florida Statutes*
Section 465.016(1) (l), F. S., prohibits a pharmacy from placing into stock any part of any prescription compounded or dispensed which is returned by a patient; however, in a hospital, nursing home, correctional facility, or extended care facility in which dispensed unit dose medication is transferred to the facility for administration, these may be returned.

*Chapter 499, Florida Statutes*
The Florida Drug and Cosmetic Act is codified in chapter 499, F. S. The act defines "wholesale distribution" to mean distribution of prescription drugs to persons other than a consumer or patient, but does not include specified activities. Chapter 499, F. S., provides safeguards for the public health and protection from injury by product use and by merchandising deceit involving drugs, devices, and cosmetics. The chapter provides uniform legislation to be administered so far as practicable in conformity with the provisions of, and regulations issued under the authority of, the Federal Food, Drug, and Cosmetic Act and that portion of the Federal Trade Commission Act which expressly prohibits the false advertisement of drugs, devices and cosmetics.

*Section 499.014, Florida Statutes*
Authorizes the distribution of prescription drugs by a charitable organization under a limited permit issued by the Department of Health.

*Section 893.13, Florida Statutes*
Provides that, except as authorized by chapter 893, F. S., (i.e., Drug Abuse Prevention and Control) and chapter 499, F. S., it is unlawful for any person to sell, manufacture, or deliver, or possess with intent to sell, manufacture, or deliver, a controlled substance.

*Florida Administrative Code*
The Department of Health has adopted rules governing the issuance of a restricted prescription drug distribution permit for charitable organizations, and for the operation of their organizations under this permit.[14]

Relevant Government Agencies

*U.S. Food and Drug Administration (FDA)*
The FDA is the federal agency responsible for ensuring that foods, drugs, biological products, and medical devices are safe and effective. Under section 505 of Federal Food, Drug, and Cosmetic Act, (FDA) no drug can be introduce or deliver for introduction into interstate commerce unless approved by the FDA.

[14] Rules 64F-12.015(8)(c) and 64F-12.023(1)., F.A.C.

The FDA has no specific regulations regarding cancer drug donation programs and leaves the cancer donation program to the discretion of the state as long as the state enforces applicable regulations relating to prescription medication.[15]

*Department of Health*
The Bureau of Statewide Pharmaceutical Services is responsible for enforcing Florida's Drug and Cosmetic Act, chapter 499, Florida Statutes. The purpose of this act is to safeguard the health of the public and protect the public from injury by product use and merchandising deceit involving drugs, devices and cosmetics, as well as false and misleading advertising. The bureau also provides pharmaceuticals to county health departments annually and administers the State of Florida's pharmaceutical contracts.

*Agency for Health Care Administration*
Hospitals are subject to oversight by the Agency for Health Care Administration and most are accredited by the Joint Commission for Healthcare Organizations. These entities have policies for reviewing pharmacy operations in hospitals.

C. SECTION DIRECTORY:

**Section 1.** Creates s. 381.94, F. S., to establish the Cancer Drug Donation Program under the Department of Health.

**Section 2.** Establishes an effective date for July 1, 2006.

## II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   According to DOH, 1 full-time equivalent position is needed to create and maintain the registry, to provide consultation and technical assistance, and to perform other administrative functions.

| | FY 06-07 | FY 07-08 |
|---|---|---|
| Salary and Expenses | ($65,308) | ($71, 079) |

The bill includes a specific appropriation of $65,308 from the General Revenue Fund for FY 2006-07 to DOH to administer the program.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

[15] Telephone discussion with FDA concerning HB 371, Stewart Watson, REHS LCDR, USPHS, Public Affairs Specialist Florida District – FDA.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

For a hospital pharmacy that elects or volunteers to participate in the program, there will be costs associated with the processing, storage, dispensing and disposal of donated cancer drugs and supplies. These costs could be recovered fully or in part by the handling fee authorized in the bill to cover the cost of preparing and dispensing the cancer drugs or supplies under the program. The fee will be established in rules adopted by DOH.

D. FISCAL COMMENTS:

According to DOH, to dispense donated drugs to eligible recipients, participating hospital pharmacies will be required to obtain a Community Pharmacy Permit, thus incurring an additional cost of $255.00 for licensure.

## III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not require counties or municipalities to spend funds or to take any action requiring the expenditure of funds. This bill does not reduce the percentage of a state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The act authorizes DOH to adopt implementing rules to include the following:

- Eligibility criteria, including a method to determine priority of eligible patients under the program.
- Standards and procedures for participants that accept, store, distribute, or dispense donated cancer drugs or supplies.
- Necessary forms for administration of the program, including, but not limited to, forms for use by persons or entities that donate, accept, distribute, or dispense cancer drugs or supplies under the program.
- The maximum handling fee that may be charged by a participant facility that accepts and distributes or dispenses donated cancer drugs or supplies.
- Categories of cancer drugs and supplies that the program will accept for dispensing.
- Categories of cancer drugs and supplies that the program will not accept for dispensing and the reason that such drugs and supplies will not be accepted.
- Maintenance and distribution of the participant registry.

However, the bill does not provide DOH with any guidance as part of this delegated authority. The bill gives the agency broad discretion on formulating rules.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

## IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

On March 15, 2006, the Judiciary Committee adopted two amendments and reported the bill favorably as a Committee Substitute. The CS differs from the CS as reported by the Health Care Committee in the following ways:

1) Reverts back to the liability provisions found in the original bill as filed. The amendment immunizes donors of cancer drugs or supplies and program participants from civil and criminal liability and professional disciplinary action when they exercise reasonable care in donating, accepting, distributing, or dispensing cancer drugs or supplies.

2) Limits non-liability to pharmaceutical manufacturers and only for injuries resulting from the transfer of any cancer drug under this program. The CS removes manufacturers of cancer supplies from this provision.

3) Provides an appropriation of $65,308 from the General Revenue Fund to the Department of Health to administer the program.

On January 11, 2006, the Health Care General Committee adopted one amendment to the bill. The amendment:

- Restricts cancer drugs to those approved by the FDA.
- Defines closed drug delivery system.
- Changes the definition of "donor" to include only cancer drugs that have been maintained within a closed drug delivery system.
- Defines "nursing home."
- Changes the definition of "participant facility" to mean a class II institutional hospital pharmacy.
- Strengthens provisions to ensure the integrity of a donated drug.
- Provides that a donation of cancer drugs can be made only at a participant facility.
- Allows DOH to exclude any drug based on its therapeutic effectiveness or high potential for abuse or diversion.
- Excludes a person receiving Medicaid or any other prescription drug program funded in whole or in part by the federal government (e.g., Medicare), or by any other prescription drug program offered by a third-party insurer, unless benefits have been exhausted, or a certain cancer drug or cancer supply is not covered by the prescription drug program.
- Requires DOH to maintain a cancer drug donation program web site and links to cancer supply manufacturers that offer drug assistance programs or offer free medication.
- Adds cancer supply manufacturers to those immune from liability for any claim or injury arising from the donation and use of any donated cancer drug.
- Provides that if any conflict exists between the provisions contained in s. 381.94, F. S., and provisions in chapter 465, F. S., or chapter 499, F. S., the provisions contained in s. 381.94, F. S., shall control the operation of the Cancer Drug Donation Program.

As amended, the bill was reported favorably as a committee substitute.

CHAMBER ACTION

The Judiciary Committee recommends the following:

**Council/Committee Substitute**

Remove the entire bill and insert:

A bill to be entitled

An act relating to the Cancer Drug Donation Program; creating s. 381.94, F.S.; providing a short title; creating the Cancer Drug Donation Program; providing a purpose; providing definitions; providing conditions for the donation of cancer drugs and supplies to the program; providing conditions for the acceptance of cancer drugs and supplies into the program, inspection of cancer drugs and supplies, and dispensing of cancer drugs and supplies to eligible patients; requiring a participant facility that accepts donated drugs and supplies through the program to comply with certain state and federal laws; authorizing a participant facility to charge fees under certain conditions; requiring the Department of Health, upon recommendation of the Board of Pharmacy, to adopt certain rules; providing for the ineligibility of certain persons to receive donated drugs; requiring the department to establish and maintain a participant facility registry; providing for the contents and availability of the

participant facility registry; providing immunity from civil and criminal liability for donors or pharmaceutical manufacturers in certain circumstances; providing that in the event of conflict between the provisions in s. 381.94, F.S., and provisions in ch. 465 or ch. 499, F.S., the provisions in s. 381.94, F.S., shall control; providing an appropriation; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 381.94, Florida Statutes, is created to read:

381.94 Cancer Drug Donation Program.--

(1) This section may be cited as the "Cancer Drug Donation Program Act."

(2) There is created a Cancer Drug Donation Program within the Department of Health for the purpose of authorizing and facilitating the donation of cancer drugs and supplies to eligible patients.

(3) As used in this section:

(a) "Cancer drug" means a prescription drug that has been approved under s. 505 of the federal Food, Drug, and Cosmetic Act and is used to treat cancer or its side effects or is used to treat the side effects of a prescription drug used to treat cancer or its side effects. "Cancer drug" does not include a substance listed in Schedule II, Schedule III, Schedule IV, or Schedule V of s. 893.03.

(b) "Closed drug delivery system" means a system in which the actual control of the unit-dose medication package is maintained by the facility rather than by the individual patient.

(c) "Department" means the Department of Health.

(d) "Donor" means a patient or patient representative who donates cancer drugs or supplies needed to administer cancer drugs that have been maintained within a closed drug delivery system; health care facilities, nursing homes, hospices, or hospitals with closed drug delivery systems; or pharmacies, drug manufacturers, medical device manufacturers or suppliers, or wholesalers of drugs or supplies, in accordance with this section. "Donor" includes a physician licensed under chapter 458 or chapter 459 who receives cancer drugs or supplies directly from a drug manufacturer, drug wholesaler, or pharmacy.

(e) "Eligible patient" means a person who the department determines is eligible to receive cancer drugs from the program.

(f) "Health care facility" means a health care facility licensed under chapter 395.

(g) "Health care clinic" means a health care clinic licensed under part XIII of chapter 400.

(h) "Hospice" means a corporation licensed under part VI of chapter 400.

(i) "Hospital" means a facility as defined in s. 395.002 and licensed under chapter 395.

(j) "Nursing home" means a facility licensed under part II of chapter 400.

(k) "Participant facility" means a class II hospital pharmacy that has elected to participate in the program and that accepts donated cancer drugs and supplies under the rules adopted by the department for the program.

(l) "Pharmacist" means a person licensed under chapter 465.

(m) "Pharmacy" means an entity licensed under chapter 465.

(n) "Prescribing practitioner" means a physician licensed under chapter 458 or any other medical professional with authority under state law to prescribe cancer medication.

(o) "Prescription drug" means a drug as defined in s. 465.003(8).

(p) "Program" means the Cancer Drug Donation Program created by this section.

(q) "Supplies" means any supplies used in the administration of a cancer drug.

(4) Any donor may donate cancer drugs or supplies to a participant facility that elects to participate in the program and meets criteria established by the department for such participation. Cancer drugs or supplies may not be donated to a specific cancer patient, and donated drugs or supplies may not be resold by the program. A participant facility may provide dispensing and consulting services to individuals who are not patients of the hospital.

(5) The cancer drugs or supplies donated to the program may be prescribed only by a prescribing practitioner for use by an eligible patient and may be dispensed only by a pharmacist.

(6)(a) A cancer drug may only be accepted or dispensed under the program if the drug is in its original, unopened, sealed container, or in a tamper-evident unit-dose packaging, except that a cancer drug packaged in single-unit doses may be accepted and dispensed if the outside packaging is opened but the single-unit-dose packaging is unopened with tamper-resistant packaging intact.

(b) A cancer drug may not be accepted or dispensed under the program if the drug bears an expiration date that is less than 6 months after the date the drug was donated or if the drug appears to have been tampered with or mislabeled as determined in paragraph (c).

(c) Prior to being dispensed to an eligible patient, the cancer drug or supplies donated under the program shall be inspected by a pharmacist to determine that the drug and supplies do not appear to have been tampered with or mislabeled.

(d) A dispenser of donated cancer drugs or supplies may not submit a claim or otherwise seek reimbursement from any public or private third-party payor for donated cancer drugs or supplies dispensed to any patient under the program, and a public or private third-party payor is not required to provide reimbursement to a dispenser for donated cancer drugs or supplies dispensed to any patient under the program.

(7)(a) A donation of cancer drugs or supplies shall be made only at a participant facility. A participant facility may decline to accept a donation. A participant facility that accepts donated cancer drugs or supplies under the program shall comply with all applicable provisions of state and federal law

relating to the storage and dispensing of the donated cancer drugs or supplies.

(b) A participant facility that voluntarily takes part in the program may charge a handling fee sufficient to cover the cost of preparation and dispensing of cancer drugs or supplies under the program. The fee shall be established in rules adopted by the department.

(8) The department, upon the recommendation of the Board of Pharmacy, shall adopt rules to carry out the provisions of this section. Initial rules under this section shall be adopted no later than 90 days after the effective date of this act. The rules shall include, but not be limited to:

(a) Eligibility criteria, including a method to determine priority of eligible patients under the program.

(b) Standards and procedures for participant facilities that accept, store, distribute, or dispense donated cancer drugs or supplies.

(c) Necessary forms for administration of the program, including, but not limited to, forms for use by entities that donate, accept, distribute, or dispense cancer drugs or supplies under the program.

(d) The maximum handling fee that may be charged by a participant facility that accepts and distributes or dispenses donated cancer drugs or supplies.

(e) Categories of cancer drugs and supplies that the program will accept for dispensing; however, the department may exclude any drug based on its therapeutic effectiveness or high potential for abuse or diversion.

(f) Maintenance and distribution of the participant facility registry established in subsection (10).

(9) A person who is eligible to receive cancer drugs or supplies under the state Medicaid program or under any other prescription drug program funded in whole or in part by the state, by any other prescription drug program funded in whole or in part by the Federal Government, or by any other prescription drug program offered by a third-party insurer, unless benefits have been exhausted, or a certain cancer drug or supply is not covered by the prescription drug program, is ineligible to participate in the program created under this section.

(10) The department shall establish and maintain a participant facility registry for the program. The participant facility registry shall include the participant facility's name, address, and telephone number. The department shall make the participant facility registry available on the department's website to any donor wishing to donate cancer drugs or supplies to the program. The department's website shall also contain links to cancer drug manufacturers that offer drug assistance programs or free medication.

(11) Any donor of cancer drugs or supplies, or any participant in the program, who exercises reasonable care in donating, accepting, distributing, or dispensing cancer drugs or supplies under the program and the rules adopted under this section shall be immune from civil or criminal liability and from professional disciplinary action of any kind for any injury, death, or loss to person or property relating to such activities.

(12) A pharmaceutical manufacturer is not liable for any claim or injury arising from the transfer of any cancer drug under this section, including, but not limited to, liability for failure to transfer or communicate product or consumer information regarding the transferred drug, as well as the expiration date of the transferred drug.

(13) If any conflict exists between the provisions in this section and the provisions in chapter 465 or chapter 499, the provisions in this section shall control the operation of the Cancer Drug Donation Program.

Section 2. There is hereby appropriated one full-time equivalent position at salary rate 42,715 and recurring funding from the General Revenue Fund in the sum of $65,308 for fiscal year 2006-2007, for the purpose of implementing the Cancer Drug Donation Program under s. 381.94, Florida Statutes, as created by this act.

Section 3. This act shall take effect July 1, 2006.

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. (for drafter's use only)

Bill No. **HB 371 CS**

COUNCIL/COMMITTEE ACTION

| | |
|---|---|
| ADOPTED | __ (Y/N) |
| ADOPTED AS AMENDED | __ (Y/N) |
| ADOPTED W/O OBJECTION | __ (Y/N) |
| FAILED TO ADOPT | __ (Y/N) |
| WITHDRAWN | __ (Y/N) |
| OTHER | _____ |

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Council/Committee hearing bill: Health Care Appropriations

Representative Harrell offered the following:

**Amendment (with title amendment)**

On line(s) 34 and 36 remove "381.94" and insert: 499.029

========== T I T L E  A M E N D M E N T ==========

On line(s) 7, 27 and 29 remove "381.94" and insert: 499.029

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HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. (for drafter's use only)

Bill No. **HB 371 CS**

COUNCIL/COMMITTEE ACTION

| | |
|---|---|
| ADOPTED | __ (Y/N) |
| ADOPTED AS AMENDED | __ (Y/N) |
| ADOPTED W/O OBJECTION | __ (Y/N) |
| FAILED TO ADOPT | __ (Y/N) |
| WITHDRAWN | __ (Y/N) |
| OTHER | _____ |

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Council/Committee hearing bill: Health Care Appropriations

Representative Harrell offered the following:

**Amendment (with title amendment)**

Remove line(s) 199-204 and insert:

Section 2. There is hereby appropriated one full-time equivalent position at salary rate 42,715 and recurring funding from the Florida Drug, Device, and Cosmetic Trust Fund pursuant to s. 499.057, Florida Statutes, in the sum of $65,308 for fiscal year 2006-2007, for the purpose of implementing the Cancer Drug Donation Program under s. 499.029, Florida Statutes, as created by this act.

## HOUSE OF REPRESENTATIVES STAFF ANALYSIS

**BILL #:** HB 577 Medicaid Comprehensive Geriatric Fall Prevention Program
**SPONSOR(S):** Garcia
**TIED BILLS:** **IDEN./SIM. BILLS:** SB 1000

| REFERENCE | ACTION | ANALYST | STAFF DIRECTOR |
|---|---|---|---|
| 1) Elder & Long-Term Care Committee | 8 Y, 0 N | DePalma | Walsh |
| 2) Health Care Appropriations Committee | | Speir | Massengale |
| 3) Health & Families Council | | | |
| 4) | | | |
| 5) | | | |

## SUMMARY ANALYSIS

House Bill 577 creates s. 409.91212, F.S., entitled the "Medicaid comprehensive geriatric fall prevention program," and directs the Agency for Health Care Administration (AHCA) to establish a Medicaid comprehensive geriatric fall prevention program in Broward and Miami-Dade Counties.

The bill requires AHCA to evaluate the cost-effectiveness and clinical effectiveness of the program before reporting its findings to the President of the Senate and the Speaker of the House of Representatives by January 1, 2009.

The bill provides for reimbursement on the same basis as provided for under the demonstration project contracts. Beginning in the third year of program implementation, however, services are to be reimbursed only on a capitated, risk-adjusted basis.

The bill provides legislative intent for incorporation of the program into the Medicaid program, and inclusion of the program as a requirement for certification or credentialing of health plans participating in either Florida Senior Care, per s. 409.912(5), F.S., or the Medicaid managed care pilot program, per s. 409.91211, F.S.

This bill has a recurring fiscal impact of $6.5 million ($2.7 million General Revenue).

The bill provides an effective date of July 1, 2006.

## FULL ANALYSIS

## I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

**Provide Limited Government**—The bill requires the Agency for Health Care Administration to establish a Medicaid comprehensive geriatric fall prevention program in Broward and Miami-Dade Counties.

**Empower Families**—Potentially, the fall prevention and education features of the bill might have the effect of enabling more Medicaid-eligible seniors to remain in community-based settings, thereby avoiding placement in various nursing and long-term care facilities, as well as decreasing reliance on more expensive Medicaid programs.

B. EFFECT OF PROPOSED CHANGES:

**BACKGROUND**

**The Incidence and Complications of Geriatric Falls**

Nationally, 12 million seniors fall each year.[1] In recent years, Florida has the second highest incidence of deaths because of geriatric falls in the United States.[2] Statewide, there were 51,079 hospital discharges for falls involving seniors 65 and older in 2004, resulting in an average hospitalization of 5.1 days, an average charge per stay of $28,018 and a total cost of $1,431,148,249.[3]

Moreover, the frequency and severity of geriatric falls is most pronounced for seniors in nursing homes and other long-term care facilities. While roughly one-third of seniors fall annually, as many as three-fourths of nursing home residents experience fall-related injuries every year.[4] A typical 100-bed nursing facility annually reports between 100-200 resident falls, while many other falls remain unreported.[5]

Deteriorating health conditions are partially responsible for increases in the frequency and severity of geriatric falls, as a senior's balance can be substantially affected by diabetes, heart disease, and poor circulation, or by medical complications affecting a senior's thyroid or nervous system.[6] The likelihood of a severe fall episode is further increased through the routine administration of medicines, and the consequences of a fall are greatly exacerbated by a senior's osteoporosis, a disease which leaves the body's bones thin and brittle, and more susceptible to easy breaks—including hip fractures.[7] Of all fall-

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[1] Testimony before United States Senate Subcommittee on Aging of David W. Fleming, Acting Director of Centers for Disease Control and Prevention, June 11, 2002, available at: http://www.cdc.gov/washington/testimony/ag061102.htm.
[2] *The State of Florida Medicaid Geriatric Fall Prevention Project; Request for Proposals*, Agency for Health Care Administration, Division of Medicaid.
[3] As reported by the Agency for Health Care Administration, using diagnosis codes E880 – E888.9. These figures only represent inpatient discharges, and not emergency department visits not resulting in an inpatient stay. Moreover, total costs reported do not include rehabilatory and accompanying costs associated with a fall, and do not include other long-term consequences of fall-related injuries, such as disability, decreased productivity or reduced quality of life.
[4] *A Tool Kit to Prevent Senior Falls: Falls in Nursing Homes*, accessed January 24, 2005, National Center for Injury Preventions and Control, Department of Health and Human Services Centers for Disease Control and Prevention, available at: http://www.cdc.gov/ncipc/factsheets/nursing.htm.
[5] Ibid.
[6] *Age Page: Preventing Falls and Fractures*, accessed January 24, 2005, National Institute on Aging, available at: http://www.niapublications.org/agepages/PDFs/Preventing_Falls_and_Fractures.pdf.
[7] Ibid.

related fractures, hip fractures result in the greatest number of deaths and are responsible for the most diminished quality of life following recovery.[8]

In a 2002 request for proposals to implement a Medicaid Geriatric Fall Prevention Demonstration Project, the Agency for Health Care Administration noted that "[f]alls and their aftermath are directly correlated with the increased utilization of health care services and increased health care costs."[9] Among seniors age 75 and older, those experiencing a fall are four to five times more likely to be admitted to a long-term care facility for a period exceeding one year,[10] and hospital stays are almost two times as long for elderly patients who are hospitalized after a fall than for other elders admitted for another reason.[11] The National Center for Injury Prevention and Control has indicated that the total cost of all fall-related injuries to seniors age 65 and older to be $27.3 billion, and by 2020 this figure is estimated to reach $43.8 billion nationally.[12] In Florida, the direct medical and long-term care costs associated with fall-related injuries was approximately $1.8 billion in 2000, and the per-fall cost to seniors age 65 and older was $10,186.[13]

**Florida Injury Prevention Program for Seniors (FLIPS)**

The Florida Injury Prevention Program for Seniors (FLIPS) is an education and awareness initiative that focuses on preventing injuries from falls and fires. The program is an interdepartmental, collaborative partnership effort among the Department of Elder Affairs, Department of Health and the Fire Marshal's Office of the Department of Financial Services that coordinates with various universities, the Florida Student Nurses Association, hospitals, county health departments and many other local agencies and organizations.

Presently, the program actively pursues "cost-avoidance activities" by conducting training workshops throughout the state, and disseminates injury prevention information to agencies serving Florida's seniors, families, friends and caregivers through operation of its "FLIPS Clearinghouse." Additionally, although the program itself does not provide direct services to high-risk individuals, the clearinghouse provides resources for case managers, social workers, home health care nurses and other individuals who deliver care to homebound seniors. Some of the brochures published by FLIPS include:

- "What Is FLIPS?"
- "Afraid of Falling Down? Try Tai Chi"
- "Medication & Poison for Elders"
- "Can Eating Right Prevent Falls?"

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[8] *Falls and Hip Fractures Among Older Adults*, accessed January 24, 2005, National Center for Injury Preventions and Control, Department of Health and Human Services Centers for Disease Control and Prevention, available at: http://www.cdc.gov/ncipc/factsheets/falls.htm..

[9] *The State of Florida Medicaid Geriatric Fall Prevention Project; Request for Proposals*, Agency for Health Care Administration, Division of Medicaid.

[10] *Falls and Hip Fractures Among Older Adults*, National Center for Injury Preventions and Control, Department of Health and Human Services Centers for Disease Control and Prevention.

[11] *Falls in the Elderly*, American Family Physician, American Academy of Family Physicians.

[12] *A tool kit to Prevent Senior Falls: the Costs of Fall Injuries Among Older Adults*, accessed January 24, 2005, National Center for Injury Preventions and Control, Department of Health and Human Services Centers for Disease Control and Prevention, available at: http://www.cdc.gov/ncipc/factsheets/fallcost.htm. The Center includes in its calculations out-of-pocket expenses and charges paid by insurance companies for the treatment of fall-related injuries, and notes that the figures do not account for the long-term consequences of fall-related injuries, such as disability, decreased productivity or reduced quality of life.

[13] *Falls Among Older Persons and the Role of the Home: An Analysis of Cost, Incidence, and Potential Savings from Home Modification*, AARP Public Policy Institute, available at: http://assets.aarp.org/rgcenter/il/ib56_falls.pdf. The AARP notes that, in 2000, 137,954 falls *requiring visits to an emergency department* were observed among the approximately 2,755,000 million seniors age 65 and older in Florida.

## Medicaid Geriatric Fall Prevention Demonstration Project in Broward and Miami-Dade Counties

### Scope of the Demonstration Project

In September 2002, AHCA prepared a request for proposals to design and implement a comprehensive, multi-faceted geriatric fall prevention program to "assist community-based Medicaid beneficiaries age 65 and older that are at high risk of falling to reduce their individual risk factors to prevent falls and permit them to remain in a community-based setting."[14] AHCA further indicated that the program "should be designed to reduce the incidence, severity, and Medicaid costs associated with geriatric falls; maximize mobility; and maintain autonomy," and the successful contract bidder should have "a thorough understanding of the Medicaid population, geriatric fall risks, and risk mitigation strategies."[15]

In its request for proposals, AHCA detailed several possible program components to be provided by the contractor,[16] including, among others:

- Developing guidelines to assist AHCA and other health professionals in their assessment of an elder's fall risk.
- Providing fall preventive education to community-based elders at risk of fall.
- Creating a risk-screening assessment.
- Providing at-risk elders with fall prevention information, literature and education, and maintaining frequent follow-up contact with at-risk elders.
- Conducting home safety evaluations.
- Completing an individualized care plan for at-risk elders.
- Making referrals to health professionals when medical conditions or drug interactions are suspected by may be untreated.
- Working with various community organizations to organize fall prevention clinics.

### Implementation of the Demonstration Project

At the direction of the Legislature[17] in Fiscal Year 2002-2003, AHCA competitively procured a two-year contract with The ElderCare Companies, Inc., to implement and coordinate operation of a Medicaid Geriatric Fall Prevention Project. The program was operational from February 19, 2003 through June 14, 2003 in Broward and Miami-Dade counties, but was eventually terminated when funding was not appropriated by the Legislature in Fiscal Year 2003-04. Although the program was designed to serve an average monthly caseload of up to 6,000 Medicaid-eligible participants, only 2,320 seniors were actually screened. Of those that were screened, 1,984 participants were found at high risk of falling and 1,738 received intensive services during the project's initial three months of operation.[18]

The demonstration project was reinstated in 2004 with an appropriation by the Legislature.[19] AHCA entered into a sole-source contact[20] with The ElderCare Companies, for the period September 15, 2004

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[14] *The State of Florida Medicaid Geriatric Fall Prevention Project; Request for Proposals*, Agency for Health Care Administration, Division of Medicaid.

[15] Ibid.

[16] Although recommended components were supplied by the RFP, it also noted that the contractor was "encouraged to present a model fall prevention and risk reduction program that can serve as a best practice model and reflects the latest literature on best practices/programs."

[17] In the FY 2002-03 General Appropriations Act (Chapter 2002-394, L.O.F.), state funding and federal Medicaid funding were appropriated for demonstration projects intended "to reduce geriatric falls among community-based Medicaid recipients."

[18] *Summary of Governor's FY 2004-05 Budget Recommendations*, Agency for Health Care Administration.

[19] FY 2004-05 General Appropriations Act (Chapter 2004-268, L.O.F.).

[20] This was a fixed-price contract in the amount of $4,824,000 per year to serve 6,000 Medicaid eligible elders, at an average cost of $804 per recipient per year.

though June 30, 2006, to continue the work begun under the previous contract. Services were again provided to more than 6,000 Medicaid-eligible seniors[21] broadly representative of the Medicaid population of Broward and Miami-Dade counties, and some preliminary analyses of outcomes were conducted. The services provided by the project to these elders included:

- Conducting multi-phase fall risk assessments.
- Coordinating hundreds of group fall prevention workshops at housing complexes, churches and social service agencies.
- Mailing 12 "safety-grams" per year to each participant.
- Placing 12 reassurance and research telephone calls per year to each participant.
- Holding several nutrition and exercise workshops.
- Communicating the results of risk-screening assessments to all participants through initial mailings.
- Providing to patients' physicians the following: (1) a client review, (2) case planning documents and, (3) notification of the availability of visiting fall prevention experts in Broward and Miami-Dade counties.
- Providing post-fall counseling, fear-of-fall counseling, and fall prevention workbooks in several different languages, including English, Spanish, Creole and Russian.

However, in June 2005 the appropriation necessary for continuation of the demonstration project was vetoed by the Governor, and the contract was terminated.

**Results of the Demonstration Project and Potential Program Savings**

The ElderCare Companies submitted results from its Medicaid geriatric fall prevention demonstration project to AHCA for review, following confirmation by vendors and subcontractors, and subject to an independent CPA audit.[22]

The ElderCare Companies reported measuring the clinical effectiveness and savings achieved by the fall prevention demonstration project though a "multi-method validation study" that equally weighted treatment and control groups. From January 2003 through June 2005, The ElderCare Companies reported the following figures versus proportionate mirror control groups:

- 54% reduction in hospitalizations due to fall-related fractures.
- 63% reduction in nursing home stays following an injurious fall.
- 60% reduction in long-term care costs, per case.
- 57% reduction in overall hospitalizations following an injurious fall.
- 21% reduction in hospitalization costs, per case.
- 35% reduction in inpatient rehabilitation costs.

## EFFECT OF PROPOSED CHANGES

House Bill 577 creates s. 409.91212, F.S., entitled "Medicaid comprehensive geriatric fall prevention program," requiring AHCA to establish a Medicaid comprehensive geriatric fall prevention program in Broward and Miami-Dade counties. The program, intended to expand upon the geriatric fall prevention demonstration project developed under state contracts awarded by AHCA in fiscal year 2003-2004, shall be evidence-based, serve 8,000 Medicaid recipients age 60 and older during the first year of operation, and be in operation within 120 days of the act's effective date.

[21] 6,702 Medicaid elders were recruited for the reinstated demonstration project, while 6,564 Medicaid-eligible seniors received multi-phase fall risk assessments.

[22] *A Comprehensive Geriatric Fall Prevention Program for All of Florida Medicaid's Community-Resident Elders: Establishing a Statewide, Permanent, Single-Vendor System*, August 2005, The ElderCare Companies, Inc.

The bill requires AHCA to evaluate the cost-effectiveness and clinical effectiveness of the program in a report submitted to the President of the Senate and the Speaker of the House of Representatives by January 1, 2009. If such report indicates the program is cost-effective and clinically effective, it shall also include a plan and timetable to statewide implementation. AHCA is required to consider findings from program evaluations and site visit reports of the demonstration project while evaluating the program's cost-effectiveness and clinical effectiveness.

The bill provides for reimbursement of services on the same basis as provided for under previous demonstration project contracts. Beginning on the first day of operation in the third year of program implementation, however, services are to be reimbursed only on a capitated, risk-adjusted basis.

The bill provides legislative intent for the Medicaid comprehensive geriatric fall prevention program's incorporation into the Medicaid program, and its inclusion by AHCA as a requirement for the certification or credentialing of any health plan to participate in the integrated, fixed-payment delivery system for Medicaid recipients 60 or older (Florida Senior Care)[23] or the certification or credentialing of any health plan participating in the Medicaid managed care pilot program[24] that enrolls Medicaid recipients who are at risk for experiencing a geriatric fall.

The bill provides an effective date of July 1, 2006.

C. SECTION DIRECTORY:

**Section 1.** Creates s. 409.91212, F.S., entitled "Medicaid comprehensive geriatric fall prevention program"; directs the Agency for Health Care Administration to establish a Medicaid comprehensive geriatric fall prevention program in Broward and Miami-Dade Counties; indicates such program shall expand a separate demonstration project; directs the agency to evaluate and report on the cost-effectiveness and clinical effectiveness of the program by January 1, 2009; provides guidelines for reimbursement; provides legislative intent for incorporation of the program into the Medicaid program and inclusion of the program as a requirement for certification or credentialing of participants in Florida Senior Care and the Medicaid managed care pilot program.

**Section 2.** Provides an effective date of July 1, 2006.

## II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   Federal financial participation in the Florida Medicaid Program for State Fiscal Year 2006-2007 is 58.77 percent; for every $1 the state spends, it earns $1.43 in federal funds.

2. Expenditures:

| **Non-recurring** | 2006-2007 | 2007-2008 |
|---|---|---|
| *Professional Staff* | | |
| General Revenue Fund | $1,305 | $0 |
| Administrative Trust Fund | $1,305 | $0 |

[23] S. 409.912(5), F.S.
[24] S. 409.912111, F.S.

| **Recurring** | 2006-2007 | 2007-2008 |
|---|---|---|
| *Medical/Health Care Program Analyst (1 FTE)* | | |
| General Revenue Fund | $31,330 | $31,330 |
| Administrative Trust Fund | $31,330 | $31,330 |
| *Geriatric Fall Services* | | |
| General Revenue Fund | $2,683,886 | $2,683,886 |
| Medical Care Trust Fund | $3,779,443 | $3,779,443 |
| **Total Expenditures** | | |
| General Revenue Fund | $2,685,191 | $2,683,886 |
| Medical Care Trust Fund | $3,779,443 | $3,779,443 |
| Administrative Trust Fund | $32,635 | $31,330 |

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

House Bill 577 apparently requires AHCA to contract with one or more private entities to re-establish a Medicaid comprehensive geriatric fall prevention program in Broward and Miami-Dade counties, in a manner consistent with previous geriatric fall prevention demonstration projects developed under state contracts awarded by AHCA in Fiscal Year 2003-2004.

D. FISCAL COMMENTS:

The greatest potential fiscal impact on AHCA is the bill's requirement to include comprehensive geriatric fall-prevention services as a statutorily-mandated Medicaid program making it available statewide to all Medicaid recipients. Potentially, hundreds of thousands of Floridians could be eligible for these services at a cost of $200 to $300 million per year (based on an estimate of the number of persons who are community-dwelling, Medicaid eligible, 60 years and older: 340,000 individuals at a cost of $800 per person per year.)

## III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   This bill does not appear to require counties or municipalities to take an action requiring the expenditure of funds, reduce the authority that counties or municipalities have to raise revenue in the aggregate, nor reduce the percentage of state tax shared with counties or municipalities.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

AHCA raises several points of concern in their analysis of House Bill 577. First, the agency notes that it is unclear whether the bill requires AHCA to competitively procure the Medicaid comprehensive geriatric fall prevention program, or whether the agency is simply required to award a sole-source contract to the previous contractor. The agency notes that, if it is to competitively procure this program, it may prove difficult to have the program fully operational within the 120 days mandated by the legislation.

Moreover, AHCA reports being unclear of the need for altering the reimbursement schedule, beginning in the program's third year of operation, to a "capitated, risk-adjusted" calculation. The agency notes it is unsure "what services the contractor would be at risk for, as the only service provided is geriatric fall prevention." Similarly, the Department of Elderly Affairs (DOEA) notes that the reimbursement schedule provided in the bill, which currently states reimbursement shall "be on the same basis as provided for under the demonstration project contracts described in subsection (1)," would be clarified through inclusion of the exact reimbursement rates contained in the previous demonstration project contracts.

AHCA reports the bill does not provide sufficient information to determine the scope of work required to conduct the required evaluation of the program's cost-effectiveness and clinical effectiveness, the number of years such evaluation should encompass, or the number of subjects to be evaluated.

AHCA also notes that, pursuant to the terms of the Medicaid Managed Care Pilot Program, as authorized by s. 409.91211, F.S., managed care plans may offer customized benefit packages to enrolled recipients and such packages must include those mandatory and optional services set forth in s. 409.905, F.S., and s. 409.906, F.S. There is nothing in s. 409.91211, F.S. that requires providers participating in the Medicaid Managed Care Pilot Program to offer geriatric fall prevention services. However, AHCA points out, House Bill 577 requires that the geriatric fall prevention program be available to recipients enrolled in health plans operated under s. 409.91211, F.S. Accordingly, AHCA believes that s. 409.91211, as well as the 1115 Waiver approved by the Centers for Medicare and Medicaid Services (CMS) authorized by the Managed Care Pilot Program, would need to be amended to include geriatric fall prevention services.

Additionally, the legislation requires that the geriatric fall prevention program be available to recipients enrolled in health plans operated under s. 409.912(5), F.S. (Florida Senior Care). At present, AHCA points out, geriatric fall prevention services are not included in the list of mandatory or optional services available through such integrated, fixed-payment delivery system for Medicaid recipients age 60 and older. Moreover, DOEA points out that AHCA and DOEA are not required in s. 409.912(5), F.S. to certify and credential health plans, as referenced in the bill, but rather are charged to "use a competitive procurement process to select entities to operate the integrated program."[25] DOEA recommends that this language would be more appropriate in the context of s. 409.912(5), F.S., if it created the requirement that the geriatric falls prevention program be a necessary component of the selection criteria for providers in the integrated, fixed-payment delivery system.

[25] S. 409.912(5)(b), F.S., noting that "[e]ntities eligible to submit bids include managed care organizations licensed under chapter 641, including entities eligible to participate in the nursing home diversion program, other qualified providers as defined in s. 430.703(7), F.S., community care for the elderly lead agencies, and other state-certified community service networks that meet comparable standards as defined by the agency, in consultation with the Department of Elderly Affairs and the Office of Insurance Regulation, to be financially solvent and able to take on financial risk for managed care."

Finally, s. 1902(a)(23) of the Social Security Act[26] provides that an individual may receive Medicaid services from any qualified provider willing to furnish such services. However, AHCA notes that the language of the bill is unclear as to whether recipients may freely choose a provider from which to receive certain geriatric fall prevention services. The bill only references an expansion of previously-awarded demonstration project contracts, and does not specify whether the geriatric fall prevention program may be provided through sources other than those with whom the agency previously contracted. At present, the Managed Care Pilot Program authorized by CMS permits the state to waive the requirements of s. 1902(a)(23) under certain circumstances. However, those circumstances do not currently include the provision of geriatric fall prevention services. Accordingly, AHCA reports it may need to seek additional waiver authority to implement a Medicaid comprehensive geriatric fall prevention program.

## IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

[26] 42 U.S.C.A. § 1396a.

A bill to be entitled

An act relating to a Medicaid comprehensive geriatric fall prevention program; creating s. 409.91212, F.S.; requiring the Agency for Health Care Administration to establish a Medicaid comprehensive geriatric fall prevention program; directing the agency to develop the program as an expansion of a certain pilot project conducted in Broward and Miami-Dade Counties; requiring the agency to evaluate the program and report to the Legislature; requiring a plan and timetable for statewide implementation contingent upon certain findings; specifying a timeframe for implementing a certain form of reimbursement; providing legislative intent; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 409.91212, Florida Statutes, is created to read:

409.91212 Medicaid comprehensive geriatric fall prevention program.--

(1)(a) The Agency for Health Care Administration shall establish a Medicaid comprehensive geriatric fall prevention program in Broward and Miami-Dade Counties. The program shall be evidence based and shall expand the geriatric fall prevention demonstration project developed under state contracts M0337 and M0509 that were awarded by the agency in fiscal year 2003-2004. The program shall serve 8,000 Medicaid recipients 60 years of

age or older during the first year of operation and shall be in operation within 120 days after the effective date of this act.

(b) The agency shall evaluate the cost-effectiveness and clinical effectiveness of the program and report its findings to the President of the Senate and the Speaker of the House of Representatives by January 1, 2009. If the findings indicate the program is cost-effective and clinically effective, the report shall include a plan and timetable for statewide implementation. In evaluating the cost-effectiveness and clinical effectiveness of the program, the agency must consider findings from program evaluations and site visit reports relating to the demonstration project described in paragraph (a).

(2) Services provided under subsection (1) shall be reimbursed on the same basis as provided for under the demonstration project contracts described in subsection (1). Beginning on the first day of operation in the third year of program implementation, as authorized under this section, services shall be reimbursed only on a capitated, risk-adjusted basis.

(3) It is the intent of the Legislature that the Medicaid comprehensive geriatric fall prevention program authorized by this section be incorporated into the Medicaid program, as provided under ss. 409.901-409.920, and included by the agency as a requirement for the certification or credentialing of any health plan to participate in the integrated, fixed-payment delivery system for Medicaid recipients who are 60 years of age or older as established in s. 409.912(5) and in the certification or credentialing of any health plan participating

in the Medicaid managed care pilot program as established in s. 409.91211 that enrolls Medicaid recipients who are at risk for geriatric falls.

Section 2. This act shall take effect July 1, 2006.

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. (for drafter's use only)

Bill No. **577**

COUNCIL/COMMITTEE ACTION

| | |
|---|---|
| ADOPTED | __ (Y/N) |
| ADOPTED AS AMENDED | __ (Y/N) |
| ADOPTED W/O OBJECTION | __ (Y/N) |
| FAILED TO ADOPT | __ (Y/N) |
| WITHDRAWN | __ (Y/N) |
| OTHER | _____ |

Council/Committee hearing bill: Health Care Appropriations

Representative(s) Garcia offered the following:

**Amendment (with title amendment)**

Remove line(s) 23-58 and insert:

program in Miami-Dade County. The program shall be evidence-based and shall expand the geriatric fall prevention demonstration project awarded under contract in 2002 by the Agency for Health Care Administration. The program shall serve 8,000 Medicaid recipients 60 years of age or older during the first year of operation and shall be in operation within 120 days after the effective date of this act.

(b) The agency shall evaluate the cost-effectiveness and clinical effectiveness of the program and report its findings to the President of the Senate and the Speaker of the House of Representatives by January 1, 2009. If the findings indicate the program is cost-effective and clinically effective, the report shall include a plan and timetable for statewide implementation. In evaluating the cost-effectiveness and clinical effectiveness of the program, the agency must consider findings from program

evaluations and site visit reports relating to the demonstration project described in paragraph (a).

(2) Services provided under subsection (1) shall be reimbursed on the same basis as provided for under the demonstration project contracts described in subsection (1). Beginning on the first day of operation in the third year of program implementation, as authorized under this section, services shall be reimbursed only on a capitated, risk-adjusted basis.

========== T I T L E A M E N D M E N T ==========

Remove line(s) 7-13 and insert:

expansion of a certain pilot project conducted in Miami-Dade County; requiring the agency to evaluate the program and report to the Legislature; requiring a plan and timetable for statewide implementation contingent upon certain findings; specifying a timeframe for implementing a certain form of reimbursement; providing an effective date.

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. (for drafter's use only)

Bill No. **577**

COUNCIL/COMMITTEE ACTION

| | |
|---|---|
| ADOPTED | __ (Y/N) |
| ADOPTED AS AMENDED | __ (Y/N) |
| ADOPTED W/O OBJECTION | __ (Y/N) |
| FAILED TO ADOPT | __ (Y/N) |
| WITHDRAWN | __ (Y/N) |
| OTHER | _____ |

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Council/Committee hearing bill: Health Care Appropriations

Representative Garcia offered the following:

**Amendment (with title amendment)**

Remove line 59 and insert:

Section 2. This act shall take effect only if a specific appropriation to fund the Medicaid comprehensive geriatric fall prevention program is made in the General Appropriations Act for Fiscal Year 2006-2007.

Section 3. If an appropriation is made pursuant to Section 2 of this act, this act shall take effect July 1, 2006.

========== T I T L E A M E N D M E N T ==========

Remove line 13 and insert:

legislative intent; providing that the act is subject to an appropriation; providing an effective date.

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## HOUSE OF REPRESENTATIVES STAFF ANALYSIS

**BILL #:** HB 595 CS Community Behavioral Health Agencies
**SPONSOR(S):** Cannon
**TIED BILLS:** **IDEN./SIM. BILLS:** SB 280

| REFERENCE | ACTION | ANALYST | STAFF DIRECTOR |
|---|---|---|---|
| 1) Judiciary Committee | 12 Y, 0 N, w/CS | Thomas | Hogge |
| 2) Health Care Appropriations Committee | | Ekholm | Massengale |
| 3) Justice Council | | | |
| 4) | | | |
| 5) | | | |

## SUMMARY ANALYSIS

The bill limits liability in negligence actions involving crisis services provided by detoxification programs, addictions receiving facilities, or designated public receiving facilities. The bill requires that net economic damages be limited to $1 million per liability claim, including, but not limited to, past and future medical expenses, wage loss, and loss of earning capacity. Additionally, any noneconomic damages are limited to $200,000 per claim.

The bill specifies that the limitations on liability enjoyed by a provider under the provisions of this act extend to an employer of the provider when the employee is acting in furtherance of the provider's responsibilities under its contract with the Department of Children and Family Services. However, these limitations are not applicable to a provider or employee who acts in a culpably negligent manner or with willful and wanton disregard or unprovoked physical aggression when such acts result in injury or death.

The bill requires each provider to obtain and maintain liability insurance coverage in the amount of $1 million per claim and $3 million per incident.

Conditional limitations on damages specified by the act are increased at the rate of 5 percent each year, to be prorated from its effective date to the date at which damages subject to such limitations are awarded by final judgment or settlement.

The effective date of this bill is July 1, 2006.

The bill does not appear to have a fiscal impact on state or local government.

## FULL ANALYSIS

## I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

**Provide limited government**—The bill mandates that each provider obtain and maintain liability insurance coverage in the amount of $1 million per claim and $3 million per incident.

**Promote personal responsibility**—The bill limits the liability of a provider in certain civil actions.

**Empower families**—To the extent that providers reduce their costs for liability insurance and from legal immunity, the offering of services, with the attendant emotional and financial benefits, may increase for families.

B. EFFECT OF PROPOSED CHANGES:

**PRESENT SITUATION**

**Background on the Provision of Mental Health Services Prevention of Substance Abuse**

Part I of chapter 394, F.S., is the Florida Mental Health Act, also known as "the Baker Act." The Baker Act describes the criteria and process for the involuntary examination of a person who is believed to have a mental illness and, because of that illness, has refused voluntary examination or is unable to determine that an examination is necessary and is a danger to themself or others or likely to suffer from self-neglect to the degree that it endangers his or her well-being. The statute authorizes law enforcement, certain mental health clinical professionals, or the court to require that an individual be involuntarily detained for evaluation for a period up to 72 hours.

In addition to procedural requirements for involuntary examination and voluntary and involuntary treatment, the Baker Act provides a framework for the public mental health service delivery system. The "front door" to that system is the public receiving facility. Receiving facilities admit persons for involuntary examination and are defined in the statute as "any public or private facility designated by the Department of Children and Family Services (DCF) to receive and hold involuntary patients under emergency conditions or for psychiatric evaluation and to provide short-term treatment."[1] Public receiving facilities are those facilities that receive public funds specifically for Baker Act examinations. Under s. 394.459(2), F.S., receiving facilities are required to examine and provide treatment to everyone, regardless of their diagnosis or ability to pay. Public receiving facilities are usually co-located with a community mental health provider agency or a public hospital.

A crisis stabilization unit is defined as "a program that provides an alternative to inpatient hospitalization and that provides brief, intensive services 24 hours a day, seven days a week, for mentally ill individuals who are in an acutely disturbed state."[2] The definition of "crisis stabilization unit" and licensure requirements for these programs are found in part IV of chapter 394, F.S., the Community Substance Abuse and Mental Health Services Act.

Part V of chapter 397, F.S., provides criteria and procedures for the involuntary admission of an individual in an acute substance abuse crisis. A person meets the criteria for involuntary admission if he or she is substance abuse impaired and because of such impairment has lost the power of self-control with respect to substance use and either is likely to harm himself or herself or others or is in need of substance abuse services and his or her judgment has been so impaired that the person is

[1] Section 394.455(26), F.S.
[2] Section 394.67(5), F.S.

unable to appreciate the need for treatment or services.[3] An individual may be compelled to emergency admission for detoxification, assessment, or stabilization through one of several pathways including law enforcement, physician certification, parent or guardian consent, or court order.

Substance abuse providers may be licensed by the DCF for one or several separate service components.[4] Included in these licensed service components are detoxification programs and addictions receiving facilities. Detoxification services may be provided within a facility that is licensed as a substance abuse treatment program or in a hospital licensed under chapter 395, F.S. Addictions receiving facilities (ARFs) are state-owned, state-operated, or state-contracted programs licensed by the DCF and designated as secure facilities to provide an intensive level of care. All persons admitted to ARFs are considered clients of the DCF and their admission cannot be denied solely on the basis of their inability to contribute to the cost of their care.[5] However, admission may be denied because of failure to meet admission criteria, medical or behavioral conditions beyond management capabilities of the program, or lack of space, services, or financial resources to pay for care.[6] Detoxification services may be provided on a residential or outpatient basis to assist an individual with the physiological and psychological withdrawal from the effects of substance abuse. While most of these programs are funded by the DCF, some of them are private, for-profit organizations that receive no funding from DCF.

As of Fiscal Year (FY) 2004-2005, DCF maintained contracts with 168 substance abuse providers and 249 community mental health provider agencies. There are currently 75 public receiving facilities and 53 private receiving facilities designated by the DCF. Among the public facilities, 47 are licensed by the Agency for Health Care Administration and designated as crisis stabilization units. The agency may not issue a license to a crisis stabilization unit unless the unit receives state funds. Of the substance abuse providers, 32 provide substance abuse detoxification services and 10 are licensed as ARFs. In FY 2004-2005, services were provided to 69,059 individuals through mental health or substance abuse crisis services agencies under contract with the DCF.

Current DCF contracts specify that a provider is an independent contractor and not an agent of the department and that the provider agrees to indemnify, defend and hold the department, its agencies, officers, and employees harmless from all claims, suits, judgments, or damages including attorneys' fees arising out of any act, actions, neglect or omission by the provider, its agents or employees. According to the Florida Council for Community Health (the "Council"), approximately 98 percent of persons served by these facilities are low income, uninsured individuals, or Medicaid eligible and virtually all funding for receiving facilities comes from local, state and federal government sources.

According to the council, the cost of medical malpractice liability insurance is limiting the ability of publicly-supported community mental health and substance abuse agencies to provide critical treatment and intervention services that are relied upon by law enforcement, local communities and state agencies. The Council states that medical malpractice insurance rates for community mental health and substance abuse agencies have increased 105 percent over the past three years, approximately 35 percent per year. In some cases, 5 percent or more of a facility's operating budget is used to pay for liability insurance.

The average cost of liability insurance for a community behavioral health provider was $238,847 in FY 2002-2003. The average yearly cost in FY 2003-2004 was $355,715, and increase of 49 percent. As an example of the impact on treatment capacity, a community mental health provider could have provided an additional 1,457 bed days of crisis stabilization care in lieu of paying for liability insurance during FY 2003-2004. The following chart provided by the council shows examples of the escalation of liability insurance premiums (which includes medical malpractice, officers and directors insurance and other liability insurance) for a sample of behavioral health care providers:

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[3] Section 397.675, F.S.
[4] Section 397.311(18), F.S.
[5] Section 397.431(5), F.S.
[6] Section 397.6751, F.S.

**Sample of Community Providers' Annual Insurance Premium Increases**
**FY 2002-03 through FY 2005-06**

| Facility | FY 2002-03 Premiums | FY 2003-04 Premiums | FY 2004-05 Premiums | FY 2005-06 Premiums | % Increase from '02-03 to '05-06 |
|---|---|---|---|---|---|
| Act Corporation | $391,000 | $425,000 | $582,061 | $619,603 | 58.5% |
| Lakeview Center | $555,301 | $793,063 | $1,063,966 | $1,236,461 | 122.7% |
| Personal Enrichment | $72,315 | $225,662 | $187,556 | $159,454 | 120.5% |
| Meridian Behavioral Health | $306,364 | $420,174 | $520,896 | $543,201 | 77.3% |
| Apalachee Center | $95,630 | $247,239 | $186,031 | $272,355 | 184.8% |
| Bayview Center | $59,280 | $88,952 | $119,629 | $137,646 | 132.2% |
| Manatee Glens | $99,744 | $125,379 | $137,404 | $162,473 | 62.9% |
| LifeStream | $137,843 | $167,463 | $221,535 | $257,879 | 87.1% |
| Bridgeway | $160,250 | $281,539 | $219,817 | $238,270 | 48.7% |
| | | | | | |
| **Average Cost / % Change** | $208,636 | $308,275 | $359,877 | $403,038 | 93.18% |

Source: Florida Council for Behavioral Healthcare, Helping Florida Families in Crisis: Liability Limits for State Funded Detoxification and Public Receiving Facilities, January 1, 2006

**Report by the Department of Children and Family Services on the Experience of Public Receiving Facilities in Securing and Maintaining Medical Malpractice Insurance**

In 2004, the Florida Legislature, in proviso language in the General Appropriations Act, mandated that the DCF develop a report that reviewed the experience of public receiving facilities in securing and maintaining medical malpractice insurance. The review was to include the current cost of insurance and the rate of increase or decrease in these costs over the past three years and the experience of these facilities with lawsuits and associated awards. The department was directed to investigate whether these facilities were experiencing problems with malpractice insurance and the impact such problems have on service delivery. The department delivered the report to the Governor and the Senate and House Appropriations committees by December 31, 2004.

The report states that the median cost of insurance for public receiving facilities rose by 72.5 percent during the four years 2001 to 2004, from $15,210 in FY 2001-2002 to $26,239 in FY 2003-2004. During this same period, the reporting agencies' acute care budgets increased by 23.01 percent.

**Similar Statutory Provisions**

Liability limits and immunity provisions similar to those proposed in this bill are extended to health care[7] and other providers serving inmates of the state correctional system,[8] providers under contract with the Department of Juvenile Justice,[9] and eligible child welfare lead agencies.[10] These immunities are not applicable to a provider or employee who acts in a culpably negligent manner or with willful and wanton disregard or unproved physical aggression when such acts result in injury or death.

**EFFECT OF PROPOSED CHANGES**

The bill creates s. 394.9085, F.S., to specify that certain facilities or programs [a detoxification program defined in s. 397.311(18)(b), F.S, an addictions receiving facility defined in s. 397.311(18)(a), F.S., or a designated public receiving facility defined in s. 394.455(26), F.S.] shall have liability limits in negligence actions based on services for crisis stabilization. The bill requires that net economic damages be limited to $1 million per liability claim, including, but not limited to, past and future medical expenses, wage loss, and loss of earning capacity. The bill also specifies that damages be offset by

[7] Section 456.048, F.S.
[8] Section 946.5026, F.S.
[9] Section 985.31(5)(d), F.S.
[10] Section 409.1671(1)(h), F.S.

any collateral source payment that is paid in accordance with s. 768.76, F.S. Additionally, any noneconomic damages specified against the entities specified by this bill are limited to $200,000 per claim. The provider or its insurer must assume any costs for defending actions brought under this section.

The bill specifies that the limitations on liability enjoyed by a provider under the provisions of this act extend to an employee of the provider when the employee is acting in furtherance of the provider's responsibilities under its contract with DCF. However, these limitations are not applicable to a provider or employee who acts in a culpably negligent manner or with willful and wanton disregard or unprovoked physical aggression when such acts result in injury or death.

The bill specifies that a person who provides contractual services to DCF is not an employee or agent of the state for the purposes of chapter 440, F.S. (Worker's Compensation). The bill requires each provider to obtain and maintain liability insurance coverage in the amount of $1 million per claim and $3 million per incident.

The bill additionally specifies that the conditional limitations on damages specified by this act shall be increased at the rate of five percent each year, to be prorated from its effective date to the date at which damages subject to such limitations are awarded by final judgment or settlement.

C. SECTION DIRECTORY:

**Section 1.** Creates 768.0755, F.S., relating to behavioral provider liability.

**Section 2.** Provides that the bill takes effect on July 1, 2006.

## II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   This bill does not appear to have a fiscal impact on state revenues.

2. Expenditures:

   This bill does not appear to have a fiscal impact on state expenditures.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   This bill does not appear to have a fiscal impact on local government revenues.

2. Expenditures:

   This bill does not appear to have a fiscal impact on local government expenditures.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The provisions of this bill limit the economic damages recoverable by certain individuals who have been damaged in tort and require that certain substance abuse and mental health providers purchase general liability coverage.

The Department of Children and Family Services reports that limiting the damages awarded to an individual may have a direct positive impact on certain mental health and substance abuse providers by containing the cost of their insurance premiums, thereby reducing their administrative costs.

To the extent that providers reduce their costs for insurance and legal fees, there may be increased funding available for services. Conversely, to the extent that injured persons are not able to recover fully for their injuries, more families may be dependent on government-funded assistance programs.

D. FISCAL COMMENTS:

None.

## III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable because this bill does not appear to require counties or cities to: spend funds or take action requiring the expenditure of funds; reduce the authority of counties or cities to raise revenues in the aggregate; or reduce the percentage of a state tax shared with counties or cities.

2. Other:

**Access to Courts**

Article I, section 21 of the Florida Constitution provides: "The courts shall be open to every person for redress of any injury, and justice shall be administered without sale, denial or delay."[11] The Legislature must not unduly or unreasonably burden or restrict access. The Florida Constitution protects "only rights that existed at common law or by statute prior to the enactment of the Declaration of Rights of the Florida Constitution."[12] In order to make a colorable claim of denial of access to courts, an aggrieved party must demonstrate that the Legislature has abolished a common-law right previously enjoyed by the people of Florida and, if so, that it has not provided a reasonable alternative for redress and that there is not an "overpowering public necessity" for eliminating the right.[13]

B. RULE-MAKING AUTHORITY:

The bill does not appear to create a need for rulemaking or rulemaking authority.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

## IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

On March 28, 2006, the Judiciary Committee adopted one amendment to this bill. The amendment rewrote a portion of the original bill to:

- clarify that the bill applies to negligence actions arising out of the provision of crisis stabilization services;
- remove the provisions relating to allowing a claims bill;
- clarify that the required insurance coverage is for paying claims arising out of these negligence actions;
- address the technical drafting concerns raised in the bill analysis.

[11] *See generally* 10A FLA. JUR. 2D CONSTITUTIONAL LAW §§ 360-69.
[12] Fla. Jur. 2d., s. 360.
[13] Kluger v. White, 281 So.2d 1, 4 (Fla. 1973).

CHAMBER ACTION

The Judiciary Committee recommends the following:

**Council/Committee Substitute**

Remove the entire bill and insert:

A bill to be entitled

An act relating to community behavioral health agencies; creating s. 394.9085, F.S.; providing that certain facilities or programs have liability limits in negligence actions under certain circumstances; limiting net economic damages allowed per claim; requiring that damages be offset by collateral source payment in accordance with s. 768.76, F.S.; requiring that costs to defend actions be assumed by the provider or its insurer; specifying occasions upon which the limitations on liability enjoyed by the provider extend to the employee; requiring that providers obtain and maintain specified liability coverage; specifying that persons providing contractual services to the state are not considered agents or employees under ch. 440, F.S.; providing for an annual increase in the conditional limitations on damages; providing definitions; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 394.9085, Florida Statutes, is created to read:

394.9085 Behavioral provider liability.--

(1)(a) In any negligence action for damages for personal injury or wrongful death arising out of the provision of services for crisis stabilization brought against a detoxification program, an addictions receiving facility, or a designated public receiving facility, net economic damages shall be limited to $1 million per liability claim, including, but not limited to, past and future medical expenses, wage loss, and loss of earning capacity. In computing net economic damages, such damages shall be offset by any collateral source payment paid in accordance with s. 768.76.

(b) In any negligence action for damages for personal injury or wrongful death arising out of the provision of services for crisis stabilization brought against any detoxification program, an addictions receiving facility, or a designated public receiving facility, noneconomic damages shall be limited to $200,000 per claim.

(c) Any costs in defending actions brought under this section shall be assumed by the provider or its insurer.

(2) The limitations on liability of a detoxification program, an addictions receiving facility, or any designated public receiving facility as described in subsection (1) shall be exclusive. Such limitations apply to each employee of the provider when the employee is acting in furtherance of the provider's responsibilities under its contract with the

department. Such limitations do not apply to a provider or employee who acts in a culpably negligent manner or with willful and wanton disregard or unprovoked physical aggression if such acts result in injury or death.

(3) The eligible provider under this section must, as part of its contract, obtain and maintain an insurance policy providing a minimum of $1 million per claim and $3 million per incident in coverage for claims described in subsection (1).

(4) This section does not designate a person who provides contracted services to the department as an employee or agent of the state for purposes of chapter 440.

(5) The Legislature is cognizant of the increasing costs of goods and services each year and recognizes that fixing a set amount of compensation actually has the effect of a reduction in compensation each year. Accordingly, the conditional limitations on damages in this section shall be increased at the rate of 5 percent each year, prorated from July 1, 2006, to the date at which damages subject to such limitations are awarded by final judgment or settlement.

(6) For purposes of this section, the terms "detoxification program," "addictions receiving facility," and "receiving facility" have the same meanings as those provided in ss. 397.311(18)(b), 397.311(18)(a), and 394.455(26), respectively.

Section 2. This act shall take effect July 1, 2006.

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. (for drafter's use only)

Bill No. **595 CS**

COUNCIL/COMMITTEE ACTION

| | |
|---|---|
| ADOPTED | __ (Y/N) |
| ADOPTED AS AMENDED | __ (Y/N) |
| ADOPTED W/O OBJECTION | __ (Y/N) |
| FAILED TO ADOPT | __ (Y/N) |
| WITHDRAWN | __ (Y/N) |
| OTHER | _____ |

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Council/Committee hearing bill: Health Care Appropriations

Representative Cannon offered the following:

**Amendment (with directory and title amendments)**

Between lines 75 and 76, insert:

(7) This section shall not be construed to waive sovereign immunity for any governmental unit or other entity protected by sovereign immunity. Section 768.28 shall continue to apply to all governmental units and such entities.

========== T I T L E A M E N D M E N T ==========

Remove line 21 and insert:

providing definitions; providing construction; preserving sovereign immunity for governmental units and entities protected by sovereign immunity; providing an effective date.

## HOUSE OF REPRESENTATIVES STAFF ANALYSIS

**BILL #:** HB 645 CS Nursing Home Facilities
**SPONSOR(S):** Gelber
**TIED BILLS:** **IDEN./SIM. BILLS:** CS/SB 298

| REFERENCE | ACTION | ANALYST | STAFF DIRECTOR |
|---|---|---|---|
| 1) Health Care General Committee | 9 Y, 0 N, w/CS | Ciccone | Brown-Barrios |
| 2) Domestic Security Committee | 9 Y, 0 N, w/CS | Wiggins | Newton |
| 3) Health Care Appropriations Committee | | Speir WFS | Massengale |
| 4) Health & Families Council | | | |
| 5) | | | |

## SUMMARY ANALYSIS

House Bill 645 CS provides legislative intent to encourage all nursing homes to have emergency electrical power system capacity to allow these facilities to remain fully operational during and after an emergency and to provide care to residents evacuated from other nursing homes.

The bill specifies that the Agency for Health Care Administration (AHCA) implement a 2-year pilot program to reimburse certain nursing home facilities for the costs of installing a quick connect electrical service entry allowing a temporary generator connection. The bill also provides for reimbursement of one-half the cost—up to $15,000—to certain nursing homes for the cost of an electrical generator services contract.

The total cost of providing reimbursements under this bill is estimated to be $4 million. The reimbursement to nursing homes by AHCA, however, is subject to an appropriation.

The bill takes effect upon becoming law.

## FULL ANALYSIS

## I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

**Provide Limited Government**—The bill requires AHCA to implement a 2-year pilot program to reimburse certain nursing home facilities for the installation cost of an emergency generator and to reimburse up to a certain amount for the cost to retain a generator for emergency use.

**Empower families**—The bill provides increased safety options to individuals and families who either reside in or have family members residing in certain nursing home facilities.

**Maintain public security**—The bill increases the health safety and physical security of nursing home residents who reside in certain facilities before and during an emergency.

B. EFFECT OF PROPOSED CHANGES:

The bill creates s. 400.0627, F.S., providing legislative intent to encourage nursing home facilities to have an emergency electrical power system to allow these facilities to remain fully operational during and after an emergency and to provide care to residents evacuated from other nursing homes. The Agency for Health Care Administration is required to implement a 2-year pilot program to reimburse nursing home facilities based on certain criteria. Eligible facilities would receive state reimbursement based on available funds for the installation cost of a quick connect electrical service entry system allowing a temporary generator connection. Nursing homes that meet eligibility criteria would also be reimbursed for the reimbursement of one-half the cost—up to $15,000—for the cost of a generator services contract.

The effect of the quick connect electrical power system and the contract would be to provide eligible nursing homes despite utility power outages, with the capacity to remain fully operational during and after an emergency and provide care of residents evacuated from other nursing facilities.

To be eligible for reimbursement, a nursing home facility must meet the following criteria:

- Be located in Broward, Collier, Dade, Monroe, or Palm Beach county.
- Not be in the hurricane evacuation zone in its county.
- Not have been cited for a class I deficiency as defined in s. 400.23(8)(a), F.S., within the last 30 months preceding the application for reimbursement.
- Have the capacity, as determined by AHCA, to receive transferred residents that are evacuated, and agree to receive those transferred residents.
- Have a contract with a company that is able to supply an electrical generator.

BACKGROUND

Hurricane Evacuation Zones

Hurricane evacuation zones are predetermined geographic areas that are likely to experience destruction or severe damage, from storm surge, waves, erosion, or flooding.[1] Depending on the track of the storm, the greater the intensity of a storm (tropical storm to Category 5 hurricane) the greater the

[1] According to NOAA, storm surge maps reflect the worst case hurricane storm surge inundation (including astronomical high tide), regardless of the point of where the center of the hurricane (or tropical storm) makes landfall. No single hurricane will necessarily cause all of the flooding represented on evacuation maps. The data reflect only still-water saltwater flooding and do not take into account the effects of pounding waves that ride on top of the storm surge in locations exposed to wave action. Evacuation maps do not show areas that may be flooded by excessive rainfall-they only depict flooding that would occur as a result of the ocean level rising as well as estuaries and rivers that can be affected by hurricane storm surge.

geographic area that will experience these conditions and therefore need to be evacuated. The closer the nursing home is to the coast, the more likely that a nursing home will be located in an evacuation zone.

According to AHCA, there are 677 licensed nursing homes in Florida. During the 2005 hurricane season there were five recorded hurricanes that caused Florida evacuations. There were 21 nursing home facilities that were completely evacuated and four that were partially evacuated with a total of 1,795 patients being displaced. Only one nursing home facility was actually closed or became inactive during the entire 2005 season. There were 51 nursing home facilities that sustained some type of damage from the hurricanes. A total of 239 nursing home facilities lost power and switched to generators during the hurricane season with one additional nursing home facility losing power without the availability of a generator.[2]

AHCA estimates approximately 466 nursing facilities are not located in county hurricane evacuation zones. This represents approximately 57,000 nursing home beds or about 70 percent of capacity.

Requirements for Nursing Home Licensure—Essential Electrical System

Since July 1982, all nursing home facilities licensed under part II of chapter 400, F.S., have been required by rule to have an onsite Essential Electrical System (EES) with an onsite fuel supply of up to 64 hours.[3] The design, installation, operation, and maintenance of this EES is reviewed by AHCA.

The EES supplies electrical service to the three main electrical branches, including the Life Safety branch, the Critical Branch, and the Equipment Branch within 10 seconds of normal service interruption. As required by the National Fire Protection Association (NFPA) standards, these emergency electrical branches provide emergency electrical service to specified electrical components of the facility such as the fire alarm system, the nurse call system, the emergency egress lighting system, the exit lighting system, the magnetic door locking system, and selected critical convenience receptacles and equipment in the facility. In addition, since 1996, all new nursing home facilities and new additions to these facilities have been required to have an EES that supplies electrical power to all ventilating fans, ice making equipment, refrigeration equipment, and selected heating, ventilation, and air conditioning equipment as determined by the facility, for a period up to 72 hours of continuous service at actual load capacity of the generator.

The EES is not required to provide electrical service to the heating, ventilation, and air conditioning (HVAC) equipment of the facility nor to the general lighting or other electrical items not specifically required by the National Fire Protection Association codes and standards.

Deficiency Classifications

Section 400.23, F.S., requires AHCA to evaluate all nursing home facilities against standards and make a determination as to the degree of compliance by each licensee with the established standards adopted in rules. The agency bases its evaluation on the most recent inspection report, taking into consideration findings from other official reports, surveys, interviews, investigations, and inspections. Findings of deficient practice are classified according to the nature and the scope of the deficiency.

There are four classes of deficiencies:

- A class I deficiency is a deficiency in which immediate corrective action is necessary because the facility's noncompliance has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident receiving care in a facility.

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[2] Senate Staff Analysis and Economic Impact Statement SB 298, revised January 23, 2006

[3] FAC 59A-4.133. Of the 669 existing licensed nursing home facilities, there are 30 facilities constructed prior to 1982 that do not have an existing generator system. These facilities house only residents, who do not require any life support systems, and as such, these facilities are in compliance with all state and federal codes and standards through the use of a battery supplied emergency electrical system that supplies emergency power to the life safety components of the facility as required by NFPA 99 for 1-½ hours duration. These components include the fire alarm, nurse call, emergency egress lighting, exit lighting, and locking systems.

- A class II deficiency is a deficiency that has compromised a resident's ability to maintain or accomplish his or her highest practicable physical, mental, and psychosocial well-being, as defined by an accurate and comprehensive resident assessment, plan of care, and provision of services.
- A class III deficiency is a deficiency that will result in no more than minimal physical, mental, or psychosocial discomfort to the resident or has the potential to compromise the resident's ability to maintain or accomplish his or her highest practical physical, mental, or psychosocial well-being, as defined by an accurate and comprehensive resident assessment, plan of care, and provision of services.
- A class IV deficiency is a deficiency that will result in no more than a minor negative impact on the resident.

According to AHCA, data from the most recent 30-month period indicates that 47 facilities have received a Class I deficiency. The classification of a deficiency affects the licensure status of the facility. A conditional license is issued if a facility has one or more class I or class II deficiencies, or class III deficiencies not corrected within the time established by the Agency. In addition, a facility that is cited for a class I deficiency, two or more class II deficiencies arising from separate surveys or investigations within a 60-day period, or has had three or more substantiated complaints within a 6-month period, each resulting in at least one class I or class II deficiency, is placed on a 6-month survey cycle for the next 2-year period.

Evacuation and Transfer of Nursing Home Residents

Section 400.23(2) (g), F.S., requires AHCA to develop rules after consultation with the Department of Community Affairs that require each nursing home to develop a comprehensive emergency management plan (CEMP). At a minimum, the rules must provide for plan components that address emergency evacuation transportation; adequate sheltering arrangements; post disaster activities, including emergency power, food, and water; post disaster transportation; supplies; staffing; emergency equipment; individual identification of residents and transfer of records; and responding to family inquiries. The comprehensive emergency management plan is subject to review and approval by the local emergency management agency. During its review, the local emergency management agency must ensure that the following agencies, at a minimum, are given the opportunity to review the plan: the Department of Elder Affairs, the Department of Health, the Agency for Health Care Administration and the Department of Community Affairs. The local emergency management agency must complete its review within 60 days and either approves the plan or advices the facility of necessary revisions.

Rule 59A-4.126, F.A.C., incorporates by reference a publication (AHCA 3110-6006, March 1994) that lists the minimum criteria for a nursing home's CEMP. The CEMP must state the procedures to ensure that emergency power, whether natural gas or diesel, is supplied to the nursing home. If the fuel supply is natural gas, the plan must identify alternate means should loss of power occur that would affect the natural gas system. The plan must state the capacity of the emergency fuel system.

C. SECTION DIRECTORY:

Section 1. Creates s. 400.0627, F.S., providing legislative intent and requires the AHCA to establish a two-year pilot program to provide state financial assistance to eligible nursing home facilities to upgrade their emergency electrical power system capacity.

Section 2. Provides that the bill takes effect upon becoming a law.

## II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None

2. Expenditures:

   AHCA estimates that the cost of the pilot would be $4 million; approximately 85 nursing home facilities located in the pilot program area would be eligible to participate. This represents approximately 10,200 nursing home beds. The reimbursement cost of the 2-year pilot program is as follows:

   - $2.7 million to reimburse eligible nursing home facilities to upgrade their emergency electrical power system capacity.
   - $1.3 million to reimburse one-half the cost—up to $15,000—of a contract to secure an electrical generator.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None

2. Expenditures:

   None

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

If implemented the bill should have a positive economic effect on business that develop, sell, rent, install or provide maintenance for large electrical generators.

D. FISCAL COMMENTS:

The bill makes the reimbursement to nursing homes subject to an appropriation by the Legislature.

## III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   This bill does not require counties or municipalities to spend funds or to take any action requiring the expenditure of funds. This bill does not reduce the percentage of a state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

   None

B. RULE-MAKING AUTHORITY:

The bill provides that the AHCA may adopt rules to administer the pilot program.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None

## IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

On March 29, 2006, the Domestic Security Committee adopted an amendment that will reimburse the cost of the pre-designed electrical service entry that allows a quick connection to a temporary electrical generator based on the lowest of three bids secured by the nursing home facility. Each facility must submit copies of the three bids with its request for plan approval to the agency. The bill was reported favorably with committee substitute.

CHAMBER ACTION

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The Domestic Security Committee recommends the following:

**Council/Committee Substitute**

Remove the entire bill and insert:

A bill to be entitled

An act relating to nursing home facilities; creating s. 400.0627, F.S.; providing legislative intent; requiring the Agency for Health Care Administration to implement a pilot program to increase the emergency electrical power capacity of nursing home facilities; providing criteria for participation in the program; providing conditions for reimbursement of participating facilities; permitting inspections of certain facilities by the agency; requiring facilities to comply with current codes and standards when modifying emergency electrical power systems; authorizing the agency to adopt rules; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 400.0627, Florida Statutes, is created to read:

400.0627 Emergency electrical power system capacity.--

(1) It is the intent of the Legislature that each nursing home facility in this state be encouraged to have an emergency electrical power system capacity that is sufficient to remain fully operational during and after an emergency in order to maintain the safety and health of the residents of the nursing home facility and, if necessary, to provide care to residents evacuated from other nursing home facilities.

(2) By July 1, 2006, the Agency for Health Care Administration shall commence implementation of a 2-year pilot program to provide the capability for increasing the capacity of emergency electrical power systems of nursing home facilities. To participate in the pilot program a nursing home facility must:

(a) Be located in Broward County, Collier County, Dade County, Monroe County, or Palm Beach County;

(b) Not be located within a hurricane evacuation zone;

(c) Not have been cited for a class I deficiency within the 30 months preceding the commencement date of implementation of the pilot program;

(d) Be capable of accepting and agree to accept at least 30 residents who are transferred from other nursing home facilities pursuant to applicable life safety and firesafety laws as determined by the agency. During any such evacuation, the facility from which the residents are transferred shall provide the receiving facility with the staff required to care for the transferred residents; and

(e) Have a contract with a company that is able to supply an electrical generator when needed.

(3)(a) A nursing home facility must notify the agency if it seeks to participate in the pilot program. If a facility providing such a notice meets the criteria in subsection (2) and funds are available as specified in paragraph (b), the agency shall reimburse the facility for one-half the cost up to $15,000 of the contract described in paragraph (2)(e) to secure an electrical generator within the 2-year duration of the pilot program. The agency shall also reimburse the facility for the cost incurred to install a permanent, predesigned electrical service entry that will allow a quick connection to a temporary electrical generator. The connection must be installed inside a permanent metal enclosure that is rated as suitable for the purpose of providing such an entry, may be located on the exterior of the building, and must be adequate to allow the operation of the facility under normal conditions. Before any such reimbursement, the facility must provide the agency with documentation that the installation is complete and the electrical work associated with the installation was performed by a certified electrical contractor.

(b) Reimbursement to a facility under paragraph (a) is available to the extent that funds are appropriated for each of the 2 years of the pilot program. Funds shall be provided to eligible facilities on a first-come, first-served basis.

(c) Subject to appropriation, the agency shall reimburse the facility for the cost of the predesigned electrical service entry that allows a quick connection to a temporary electrical generator based on the lowest of three bids secured by the

facility. Each facility must submit copies of the three bids to the agency with its request for plan approval.

(4) A nursing home facility that participates and is reimbursed for an installation under the pilot program shall ensure the proper safekeeping and maintenance of the installation and allow the agency access as needed to inspect the installation.

(5) This section does not require a nursing home facility to participate in the pilot program or to modify the capacity of its existing emergency electrical power system. However, if the existing emergency electrical power system of a nursing home facility is modified as part of an installation for which reimbursement is provided under subsection (3), such system must comply with all current codes and standards.

(6) The agency may adopt rules pursuant to ss. 120.536 and 120.54 to implement the provisions of this section.

Section 2. This act shall take effect upon becoming a law.

# HOUSE OF REPRESENTATIVES STAFF ANALYSIS

**BILL #:** HB 715 CS Trauma Services
**SPONSOR(S):** Grimsley
**TIED BILLS:** **IDEN./SIM. BILLS:**

| REFERENCE | ACTION | ANALYST | STAFF DIRECTOR |
|---|---|---|---|
| 1) Health Care Regulation Committee | 9 Y, 0 N, w/CS | Bell | Mitchell |
| 2) Health Care Appropriations Committee | | Money | Massengale |
| 3) Health & Families Council | | | |
| 4) | | | |
| 5) | | | |

## SUMMARY ANALYSIS

The 2005 Legislature passed House Bill 497 and House Bill 1697, which provided additional funding to trauma centers through traffic infraction fines and court assessments. Revenues generated through these additional funds are appropriated into the Department of Health (DOH) Administrative Trust Fund, from which up to $7.5 million is earmarked to provide funding for trauma centers on the basis of caseload and the severity of trauma patients. Currently, $1 million has been raised by the increased fee.

House Bill 715 CS addresses the allocation and distribution of trauma center funds. The bill changes a number of provisions related to the distribution and determination of trauma payments to current verified trauma centers. The changes include:

- Changing the way trauma centers determine the severity of patients (by requiring trauma centers to evaluate patients with the International Classification Injury Severity Score (ICISS) instead of the Injury Severity Score (ISS)).
- Providing definitions for ICISS, trauma caseload volume, trauma patient, and local funding contribution.
- Creating a trauma center start-up grant program.

The fiscal impact of the bill is a one-time appropriation from general revenue of $500,000 for the creation of a trauma center start-up grant.

The effective date of the bill is July 1, 2006.

## FULL ANALYSIS

## I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

**Promote Limited Government**—The bill provides new definitions and changes the way verified trauma centers determine the severity of trauma patients that may alter the distribution of trauma center funds. The bill provides a one-time appropriation from general revenue of $500,000 for the creation of a trauma center start-up grant.

B. EFFECT OF PROPOSED CHANGES:

**Present Situation**

In the 2005 session the Legislature passed House Bill 497 and House Bill 1697, both of which provide additional funding to trauma centers through traffic infraction fines and court assessments. House Bill 715 CS increased the civil penalties for drivers who fail to obey red traffic signals from $60 to $125. HB 1697 allocated funds from mandatory civil penalties to provide financial support to trauma centers throughout the state.

Revenues generated through these additional funds are appropriated into the Department of Health (DOH) Administrative Trust Fund, from which up to $7.5 million is earmarked to provide funding for trauma centers on the basis of caseload and the severity of trauma patients. Currently, $1 million dollars has been raised by the increased fee.

Trauma center funding is weighted based on the severity of trauma patients (40 percent), the trauma caseload volume (40 percent), and availability of local funding contributions (20 percent). The severity of trauma patients is determined by the ISS score and the caseload volume is determined by DOH's Trauma Registry Data.

The severity of trauma patients and caseload volume is collected and entered into the Department of Health Trauma Registry. The classification currently used to rate severity of trauma is the Injury Severity Score (ISS).

Trauma Registry data is currently verified by DOH staff during the yearly trauma center site survey. The DOH survey takes a very small sample of Trauma Registry records to evaluate trauma staffing and procedures. This survey does not focus on the validity of the Trauma Registry ISS.

Currently, funds collected for distribution to trauma centers are based on the calendar year and not the state fiscal year.

The University of Florida recently published, *A Comprehensive Assessment of the Florida Trauma System*. To improve trauma care in Florida, the report recommended placing trauma centers in Tallahassee and Bay County.

**Effects of the Bill**

The bill amends s. 395, 404, and 395.4035, F.S., to address the allocation of trauma center funds. It changes a number of provisions related to the determination and distribution of trauma payments to current verified trauma centers.

The bill changes the standard by which trauma centers report injuries to DOH. Currently the severity of trauma patients is determined and coded with Injury Severity Scores (ISS), which only considers a maximum of three patient injuries. The bill requires trauma severity to be determined by the International Classification Injury Severity Scores (ICISS), the current standard, and other statistically valid and scientifically accepted methods of stratifying a trauma patient's severity of injury, risk of mortality, and resource consumption as adopted by DOH by rule. The impact of the change in injury determination methodology may change payment calculations for determining the amount of funding allotted to each trauma center.

The bill provides that DOH's Administrative Trust Fund may be used to maximize federal funds available to trauma centers. The total funds distributed to trauma centers may include revenue from DOH's Administrative Trust Fund and federal funds for which revenue from DOH's Administrative Trust Fund is used to meet state or local matching requirements, including Medicaid. Funds collected from traffic infractions and earmarked for trauma centers under s. 318.14 and 318.18, F. S., will be distributed to trauma centers on quarterly basis. The data used to distribute trauma funds will be from the most recent year available.

The bill repeals s. 395.4035, F.S., the Trauma Trust Fund. This has no impact on trauma centers because the Trauma Trust Fund has never been used by DOH. Funds collected for distribution to trauma centers have been deposited into either the Emergency Medical Services Trust Fund or the DOH Administrative Trust Fund.

The bill amends s. 395.4001, F. S., to provide definitions for the International Classification Injury Severity Score (ICISS), trauma caseload volume, trauma patient, and local funding contribution. These are new statutory definitions.

**Trauma Start-Up Grant**

The bill creates s. 395.65, F.S., to establish a trauma start-up grant program. The program recognizes that there is significant up-front investment of capital incurred by hospitals to develop the physical space, equipment, and qualified personnel necessary to provide quality trauma services. The grant program provides a one-time grant of $500,000, to be matched by local contributions, to qualifying hospitals. To qualify for the grant program a hospital must be located in a trauma region that does not currently have a trauma center and be at least 100 miles away from a current trauma center. A hospital must also meet the following criteria:

- Receive local funding contributions.
- Incur start-up costs in excess of the grant funding request.
- Actively pursue the establishment of a residency program in emergency medicine.

Hospitals receiving start-up grant funding have 24 months to become a trauma center or start-up grant funds must be returned.

BACKGROUND

Chapter 395, F.S., defines a trauma center as a facility within a general medical hospital determined by the Department of Health to be in compliance with trauma center verification standards. These centers treat individuals who have incurred blunt or penetrating injuries or burns, and who require immediate medical intervention and treatment. Trauma center patients require urgent, lifesaving care. Trauma centers must be ready at all times and have designated suites reserved to treat patients at all times. Emergency rooms are not trauma centers. A trauma center has dozens of specialists, many of whom are available 24-hours-a-day, seven days a week. Trauma centers have access to air emergency whose job is to be available for the moment a serious accident occurs.

The effectiveness of a trauma center lies in the speed and quality of treatment. Getting a patient definitive care within the first hour, or golden hour, of injury drastically increases their chances of survival. Trauma mortality is reduced by 15-20 percent when a very seriously injured patient is treated at a trauma center versus a non-trauma center.

Florida's trauma system has been under development since the passage of landmark trauma legislation in the late 1980s. Key components of this system include trauma centers, trauma agencies, trauma service areas, and trauma regions, as well as trauma transport protocols and trauma triage criteria for emergency medical service providers.

**Florida Trauma Registry**

The Florida Trauma Registry (FTR) collects patient-level data from the state's twenty-one trauma centers. As a state designated facility, a trauma center must maintain a comprehensive database of those injured patients treated within the hospital. The trauma registry supports the trauma centers required activities, including performance improvement, outcomes research, and resource utilization as well as providing the state public health system with the necessary data for state-wide planning and injury prevention initiatives.

**Comparing the Injury Severity Scores and the International Classification Injury Severity Scores**

Characterization of injury severity is crucial to the study and treatment of trauma. The measurement of injury severity began just over 50 years ago with the Abbreviated Injury Scale (AIS), a method developed to grade the severity of individual injuries. The AIS has been modified many times, most recently in 1990, and is the basis for the Injury Severity Score (ISS). The Injury Severity Score (ISS) was, for many decades, the standard summary measure of human trauma. However, it has two weaknesses. First, the ISS considers a maximum of only three of an individual patient's injuries which may not even be the patient's most severe injuries. Second, the ISS requires that all patients have their injuries described using an expensive assessment method unavailable at most hospitals, especially those that do not specialize in trauma.[1]

A more recent approach to injury scoring is based on the *International Classification of Disease, Ninth Edition* (*ICD-9*) codes and is referred to as the *ICD-9* Injury Severity Score (ICISS). The ICISS is a data-driven alternative to ISS that uses empirically-derived injury severity measures, and considers all of an individual patient's injuries rather than just a few. The use of the standard ICD-9 classification scheme adds to the statistical appeal of the ICISS and avoids the need for costly AIS coding.[2]

In terms of methodology, the ICISS uses survival risk ratios (SRRs) calculated for each *ICD-9* discharge diagnosis. SRRs are derived by dividing the number of survivors in each *ICD-9* code by the total number of patients with the same *ICD-9* code. ICISS is calculated as the simple product of the SRRs for each of the patient's injuries.[3] For example, if a population of 1,000 patients with femoral fractures included 100 patients who died, then the single SRR for that particular diagnoses would be .9 or [1-(100/1000)]. A patient with two injuries, one having a SRR of .9 and the other having a SRR of .5, would have a total probability of survival of .9 multiplied by .5, yielding an overall probability of survival of .45.[4]

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[1] Osler, T., Rutledge, R., et al. ***ICISS*: An International Classification of Disease-9 Based Injury Severity Score.** *Journal of Trauma-Injury Infection & Critical Care.* 41(3):380-388, September 1996. Available online at http://www.itrauma.com/.

[2] Sposato, E.M. "The End of the Injury Severity Score (ISS) and the Trauma and Injury Severity Score (TRISS): ICISS, an International Classification of Diseases, Ninth Revision-Based Prediction Tool, Outperforms Both ISS and TRISS as Predictors of Trauma Patient Survival, Hospital Charges, and Hospital Length of Stay. *Journal of Trauma Nursing.* Jan-March, 1999. Available online at http://www.allbusiness.com/periodicals/article/350114-1.html

[3] Offner, P. Trauma Scoring Systems. *EMedicine.* 4/25/02. http://www.emedicine.com/med/topic3214.htm

[4] https://jobs.orhs.org/trauma/report-feb-05.pdf

ICISS has demonstrated a greater reliability than ISS, and offers many advantages for predicting the severity of an illness and injury. The ICISS values may also be used as predictors of resource utilization, and may be used as an assessment tool in quality improvement efforts. Research has shown benefits of the ICISS over other scoring systems include:[5]

1. It represents a true continuous variable that takes on values between 0 and 1.
2. It includes all injuries.
3. *ICD-9* codes are readily available and do not require special training or expertise to determine.
4. *ICD-9* has better predictive power when compared to the ISS.
5. ICISS has the potential to better account for the effects of comorbidity on outcome by including the SRR for each comorbidity present.
6. The ICISS outperforms the ISS in predicting other outcomes of interest (e.g., hospital length of stay, hospital charges).
7. Compared to all over available severity adjustment systems, ICISS was most accurate.
8. ICISS can be more precisely population-based.
9. ICISS requires no additional software manipulation of data. ICDMAP-90 software for risk stratification converts International Classification of Disease (ICD) discharge diagnoses to injury severity scores to allow standardized outcome comparison.

C. SECTION DIRECTORY:

**Section 1.** Amends s. 395.4001, F.S., providing definitions.

**Section 2.** Repeals s. 395.4035, F.S.

**Section 3.** Amends s. 395.4036, F.S., providing standards for trauma center funding.

**Section 4.** Creates s. 395.65, F.S., establishing a trauma center start-up grant program.

**Section 5.** Provides a one-time appropriation of $500,000 to fund the trauma center start-up grant program.

**Section 6.** Provides the bill will take effect July 1, 2006.

## II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   The bill requires a one time-time appropriation of $500,000 from the General Revenue Fund to be deposited into the Administrative Trust Fund in the Department of Health to fund trauma center start-up grants.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

[5] http://www.emedicine.com/med/topic3214.htm and https://jobs.orhs.org/trauma/report-feb-05.pdf

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill alters the way trauma centers determine the severity of trauma patients. Forty percent of trauma center funding is distributed by the ISS coded severity of trauma patients. Thus, the bill has the potential to increase or decrease trauma center payments depending on the results of the severity ranking system. Additionally, 40 percent of trauma center funding is distributed based on trauma caseload Trauma Registry data.

D. FISCAL COMMENTS:

None.

## III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not require counties or municipalities to spend funds or take action requiring the expenditure of funds. This bill does not reduce the percentage of state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The Department of Health has sufficient rule making authority to implement the provisions in the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

## IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

On March 15, 2006 the Health Care Regulation Committee adopted a strike-all amendment and reported the bill favorably. The strike all amendment:

- Provides a definition for local funding contribution.
- Clarifies that funding distributions will be made using the most recent trauma patient data available.
- Clarifies that funds collected through traffic fines dedicated to support trauma centers will be distributed on a quarterly basis.
- Removes the proposed audit of trauma data.
- Provides $500,000 for a trauma center start-up grant.

The analysis is drafted to the committee substitute.

CHAMBER ACTION

The Health Care Regulation Committee recommends the following:

**Council/Committee Substitute**

Remove the entire bill and insert:

A bill to be entitled

An act relating to trauma services; amending s. 395.4001, F.S.; providing definitions; repealing s. 395.4035, F.S., to terminate the Trauma Services Trust Fund; amending s. 395.4036, F.S.; revising provisions relating to distribution of funds to trauma centers and use thereof; creating s. 395.65, F.S.; establishing a trauma center startup grant program; providing conditions for the receipt of a startup grant; providing limitations; providing an appropriation; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 395.4001, Florida Statutes, is amended to read:

395.4001 Definitions.--As used in this part, the term:

(1) "Agency" means the Agency for Health Care Administration.

(2) "Charity care" or "uncompensated trauma care" means that portion of hospital charges reported to the agency for which there is no compensation, other than restricted or unrestricted revenues provided to a hospital by local governments or tax districts regardless of method of payment, for care provided to a patient whose family income for the 12 months preceding the determination is less than or equal to 200 percent of the federal poverty level, unless the amount of hospital charges due from the patient exceeds 25 percent of the annual family income. However, in no case shall the hospital charges for a patient whose family income exceeds four times the federal poverty level for a family of four be considered charity.

(3) "Department" means the Department of Health.

(4) "Interfacility trauma transfer" means the transfer of a trauma victim between two facilities licensed under this chapter, pursuant to this part.

(5) "International Classification Injury Severity Score" means the statistical method for computing the severity of injuries sustained by trauma patients. The International Classification Injury Severity Score shall be the methodology used by the department and trauma centers to report the severity of an injury.

(6) ~~(5)~~ "Level I trauma center" means a trauma center that:

(a) Has formal research and education programs for the enhancement of trauma care; is verified by the department to be in substantial compliance with Level I trauma center and

pediatric trauma center standards; and has been approved by the department to operate as a Level I trauma center.

(b) Serves as a resource facility to Level II trauma centers, pediatric trauma centers, and general hospitals through shared outreach, education, and quality improvement activities.

(c) Participates in an inclusive system of trauma care, including providing leadership, system evaluation, and quality improvement activities.

(7) ~~(6)~~ "Level II trauma center" means a trauma center that:

(a) Is verified by the department to be in substantial compliance with Level II trauma center standards and has been approved by the department to operate as a Level II trauma center.

(b) Serves as a resource facility to general hospitals through shared outreach, education, and quality improvement activities.

(c) Participates in an inclusive system of trauma care.

(8) "Local funding contribution" means local municipal, county, or tax district funding exclusive of any patient-specific funds received pursuant to ss. 154.301-154.316, private foundation funding, or public or private grant funding of at least $150,000 received by a hospital or health care system that operates a trauma center.

(9) ~~(7)~~ "Pediatric trauma center" means a hospital that is verified by the department to be in substantial compliance with pediatric trauma center standards as established by rule of the

department and has been approved by the department to operate as a pediatric trauma center.

(10) ~~(8)~~ "Provisional trauma center" means a hospital that has been verified by the department to be in substantial compliance with the requirements in s. 395.4025 and has been approved by the department to operate as a provisional Level I trauma center, Level II trauma center, or pediatric trauma center.

(11) ~~(9)~~ "Trauma agency" means a department-approved agency established and operated by one or more counties, or a department-approved entity with which one or more counties contract, for the purpose of administering an inclusive regional trauma system.

(12) ~~(10)~~ "Trauma alert victim" means a person who has incurred a single or multisystem injury due to blunt or penetrating means or burns, who requires immediate medical intervention or treatment, and who meets one or more of the adult or pediatric scorecard criteria established by the department by rule.

(13) "Trauma caseload volume" means the number of trauma patients reported by individual trauma centers to the Trauma Registry and validated by the department.

(14) ~~(11)~~ "Trauma center" means a hospital that has been verified by the department to be in substantial compliance with the requirements in s. 395.4025 and has been approved by the department to operate as a Level I trauma center, Level II trauma center, or pediatric trauma center.

(15) "Trauma patient" means a person who has incurred a physical injury or wound caused by trauma and has accessed a trauma center.

(16) ~~(12)~~ "Trauma scorecard" means a statewide methodology adopted by the department by rule under which a person who has incurred a traumatic injury is graded as to the severity of his or her injuries or illness and which methodology is used as the basis for making destination decisions.

(17) ~~(13)~~ "Trauma transport protocol" means a document which describes the policies, processes, and procedures governing the dispatch of vehicles, the triage, prehospital transport, and interfacility trauma transfer of trauma victims.

(18) ~~(14)~~ "Trauma victim" means any person who has incurred a single or multisystem injury due to blunt or penetrating means or burns and who requires immediate medical intervention or treatment.

Section 2. Section 395.4035, Florida Statutes, is repealed.

Section 3. Subsection (1) of section 395.4036, Florida Statutes, is amended to read:

395.4036 Trauma payments.--

(1) Recognizing the Legislature's stated intent to provide financial support to the current verified trauma centers and to provide incentives for the establishment of additional trauma centers as part of a system of state-sponsored trauma centers, the department shall utilize funds collected under s. 318.18(15) ~~(14)~~ and deposited into the Administrative Trust Fund of the department to ensure the availability and accessibility

of trauma services throughout the state as provided in this subsection.

(a) Twenty percent of the total funds collected under this subsection during the state fiscal year shall be distributed to verified trauma centers ~~located in a region~~ that have ~~has~~ a local funding contribution as of December 31. Distribution of funds under this paragraph shall be based on trauma caseload volume for the most recent calendar year available.

(b) Forty percent of the total funds collected under this subsection shall be distributed to verified trauma centers based on trauma caseload volume for ~~of~~ the most recent ~~previous~~ calendar year available. The determination of caseload volume for distribution of funds under this paragraph shall be based on the department's Trauma Registry data.

(c) Forty percent of the total funds collected under this subsection shall be distributed to verified trauma centers based on severity of trauma patients for the most recent calendar year available. The determination of severity for distribution of funds under this paragraph shall be based on the department's International Classification Injury Severity Scores or another statistically valid and scientifically accepted method of stratifying a trauma patient's severity of injury, risk of mortality, and resource consumption as adopted by the department by rule, weighted based on the costs associated with and incurred by the trauma center in treating trauma patients. The weighting of scores shall be established by the department by rule ~~scores of 1-14 and 15 plus~~.

Funds deposited in the department's Administrative Trust Fund for verified trauma centers may be used to maximize the receipt of federal funds that may be available for such trauma centers. Notwithstanding this section and s. 318.14, distributions to trauma centers may be adjusted in a manner to ensure that total payments to trauma centers represent the same proportional allocation as set forth in this section and s. 318.14. For purposes of this section and s. 318.14, total funds distributed to trauma centers may include revenue from the Administrative Trust Fund and federal funds for which revenue from the Administrative Trust Fund is used to meet state or local matching requirements. Funds collected under ss. 318.14 and 318.18(15) and deposited in the Administrative Trust Fund of the department shall be distributed to trauma centers on a quarterly basis using the most recent calendar year data available. Such data shall not be used for more than four quarterly distributions unless there are extenuating circumstances as determined by the department, in which case the most recent calendar year data available shall continue to be used and appropriate adjustments shall be made as soon as the more recent data becomes available. ~~Trauma centers may request that their distributions from the Administrative Trust Fund be used as intergovernmental transfer funds in the Medicaid program.~~

Section 4. Section 395.65, Florida Statutes, is created to read:

395.65 Trauma center startup.--There is established a trauma center startup grant program.

(1) The Legislature recognizes the need for a statewide, cohesive, uniform, and integrated trauma system, and the Legislature acknowledges that the state has been divided into trauma service areas. Each of the trauma service areas should have at least one trauma center; however, some trauma service areas do not have a trauma center because of the significant up-front investment of capital required for hospitals to develop the physical space, equipment, and qualified personnel necessary to provide quality trauma services.

(2) An acute care general hospital that has submitted a letter of intent and an application to become a trauma center pursuant to s. 395.4025 may apply to the department for a startup grant. The grant applicant must demonstrate that:

(a) There are currently no other trauma centers in the hospital's trauma service area as established under s. 395.402.

(b) There is not a trauma center within a 100-mile radius of the proposed trauma center.

(c) The hospital has received a local funding contribution as defined under s. 395.4001.

(d) The hospital has incurred startup costs in excess of the amount of grant funding requested.

(e) The hospital is pursuing the establishment of a residency program in emergency medicine.

(3) A hospital receiving startup grant funding that does not become a provisional trauma center within 24 months after submitting an application to become a trauma center must forfeit any state grant funds received pursuant to this section.

(4) A hospital that receives startup grant funding may not receive more than $500,000, must ensure that the startup grant funding is matched on a dollar-for-dollar basis with a local funding contribution, and shall receive startup grant funding only one time.

Section 5. The sum of $500,000 is appropriated from the General Revenue Fund for deposit to the Administrative Trust Fund of the Department of Health for the 2006-2007 fiscal year for the purpose of providing trauma center startup grants under s. 395.65, Florida Statutes.

Section 6. This act shall take effect July 1, 2006.

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. (for drafter's use only)

Bill No. **715 CS**

COUNCIL/COMMITTEE ACTION

| | |
|---|---|
| ADOPTED | __ (Y/N) |
| ADOPTED AS AMENDED | __ (Y/N) |
| ADOPTED W/O OBJECTION | __ (Y/N) |
| FAILED TO ADOPT | __ (Y/N) |
| WITHDRAWN | __ (Y/N) |
| OTHER | _____ |

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Council/Committee hearing bill: Health Care Appropriations

Representative Grimsley offered the following:

**Amendment (with title amendment)**

Remove everything after the enacting clause and insert:

Section 1. Section 395.4001, Florida Statutes, is amended to read:

395.4001 Definitions.--As used in this part, the term:

(1) "Agency" means the Agency for Health Care Administration.

(2) "Charity care" or "uncompensated trauma care" means that portion of hospital charges reported to the agency for which there is no compensation, other than restricted or unrestricted revenues provided to a hospital by local governments or tax districts regardless of method of payment, for care provided to a patient whose family income for the 12 months preceding the determination is less than or equal to 200 percent of the federal poverty level, unless the amount of hospital charges due from the patient exceeds 25 percent of the annual family income. However, in no case shall the hospital charges for a patient whose family income exceeds four times the

federal poverty level for a family of four be considered charity.

(3) "Department" means the Department of Health.

(4) "Interfacility trauma transfer" means the transfer of a trauma victim between two facilities licensed under this chapter, pursuant to this part.

(5) "International Classification Injury Severity Score" means the statistical method for computing the severity of injuries sustained by trauma patients. The International Classification Injury Severity Score shall be the methodology used by the department and trauma centers to report the severity of an injury.

(6) ~~(5)~~ "Level I trauma center" means a trauma center that:

(a) Has formal research and education programs for the enhancement of trauma care; is verified by the department to be in substantial compliance with Level I trauma center and pediatric trauma center standards; and has been approved by the department to operate as a Level I trauma center.

(b) Serves as a resource facility to Level II trauma centers, pediatric trauma centers, and general hospitals through shared outreach, education, and quality improvement activities.

(c) Participates in an inclusive system of trauma care, including providing leadership, system evaluation, and quality improvement activities.

(7) ~~(6)~~ "Level II trauma center" means a trauma center that:

(a) Is verified by the department to be in substantial compliance with Level II trauma center standards and has been approved by the department to operate as a Level II trauma center.

(b) Serves as a resource facility to general hospitals through shared outreach, education, and quality improvement activities.

(c) Participates in an inclusive system of trauma care.

(8) "Local funding contribution" means local municipal, county, or tax district funding exclusive of any patient-specific funds received pursuant to ss. 154.301-154.316, private foundation funding, or public or private grant funding of at least $150,000 received by a hospital or health care system that operates a trauma center.

(9)~~(7)~~ "Pediatric trauma center" means a hospital that is verified by the department to be in substantial compliance with pediatric trauma center standards as established by rule of the department and has been approved by the department to operate as a pediatric trauma center.

(10)~~(8)~~ "Provisional trauma center" means a hospital that has been verified by the department to be in substantial compliance with the requirements in s. 395.4025 and has been approved by the department to operate as a provisional Level I trauma center, Level II trauma center, or pediatric trauma center.

(11)~~(9)~~ "Trauma agency" means a department-approved agency established and operated by one or more counties, or a department-approved entity with which one or more counties contract, for the purpose of administering an inclusive regional trauma system.

(12)~~(10)~~ "Trauma alert victim" means a person who has incurred a single or multisystem injury due to blunt or penetrating means or burns, who requires immediate medical intervention or treatment, and who meets one or more of the

adult or pediatric scorecard criteria established by the department by rule.

(13) "Trauma caseload volume" means the number of trauma patients reported by individual trauma centers to the Trauma Registry and validated by the department.

(14) ~~(11)~~ "Trauma center" means a hospital that has been verified by the department to be in substantial compliance with the requirements in s. 395.4025 and has been approved by the department to operate as a Level I trauma center, Level II trauma center, or pediatric trauma center.

(15) "Trauma patient" means a person who has incurred a physical injury or wound caused by trauma and has accessed a trauma center.

(16) ~~(12)~~ "Trauma scorecard" means a statewide methodology adopted by the department by rule under which a person who has incurred a traumatic injury is graded as to the severity of his or her injuries or illness and which methodology is used as the basis for making destination decisions.

(17) ~~(13)~~ "Trauma transport protocol" means a document which describes the policies, processes, and procedures governing the dispatch of vehicles, the triage, prehospital transport, and interfacility trauma transfer of trauma victims.

(18) ~~(14)~~ "Trauma victim" means any person who has incurred a single or multisystem injury due to blunt or penetrating means or burns and who requires immediate medical intervention or treatment.

Section 2. Section 395.4035, Florida Statutes, is repealed.

Section 3. Subsection (1) of section 395.4036, Florida Statutes, is amended to read:

395.4036 Trauma payments.--

(1) Recognizing the Legislature's stated intent to provide financial support to the current verified trauma centers and to provide incentives for the establishment of additional trauma centers as part of a system of state-sponsored trauma centers, the department shall utilize funds collected under s. 318.18(15) ~~(14)~~ and deposited into the Administrative Trust Fund of the department to ensure the availability and accessibility of trauma services throughout the state as provided in this subsection.

(a) Twenty percent of the total funds collected under this subsection during the state fiscal year shall be distributed to verified trauma centers ~~located in a region~~ that have ~~has~~ a local funding contribution as of December 31. Distribution of funds under this paragraph shall be based on trauma caseload volume for the most recent calendar year available.

(b) Forty percent of the total funds collected under this subsection shall be distributed to verified trauma centers based on trauma caseload volume for ~~of~~ the most recent ~~previous~~ calendar year available. The determination of caseload volume for distribution of funds under this paragraph shall be based on the department's Trauma Registry data.

(c) Forty percent of the total funds collected under this subsection shall be distributed to verified trauma centers based on severity of trauma patients for the most recent calendar year available. The determination of severity for distribution of funds under this paragraph shall be based on the department's International Classification Injury Severity Scores or another statistically valid and scientifically accepted method of stratifying a trauma patient's severity of injury, risk of mortality, and resource consumption as adopted by the department by rule, weighted based on the costs associated with and

incurred by the trauma center in treating trauma patients. The weighting of scores shall be established by the department by rule ~~scores of 1 14 and 15 plus~~.

Funds deposited in the department's Administrative Trust Fund for verified trauma centers may be used to maximize the receipt of federal funds that may be available for such trauma centers. Notwithstanding this section and s. 318.14, distributions to trauma centers may be adjusted in a manner to ensure that total payments to trauma centers represent the same proportional allocation as set forth in this section and s. 318.14. For purposes of this section and s. 318.14, total funds distributed to trauma centers may include revenue from the Administrative Trust Fund and federal funds for which revenue from the Administrative Trust Fund is used to meet state or local matching requirements. Funds collected under ss. 318.14 and 318.18(15) and deposited in the Administrative Trust Fund of the department shall be distributed to trauma centers on a quarterly basis using the most recent calendar year data available. Such data shall not be used for more than four quarterly distributions unless there are extenuating circumstances as determined by the department, in which case the most recent calendar year data available shall continue to be used and appropriate adjustments shall be made as soon as the more recent data becomes available. ~~Trauma centers may request that their distributions from the Administrative Trust Fund be used as intergovernmental transfer funds in the Medicaid program.~~

Section 4. Section 395.41, Florida Statutes, is created to read:

395.41 Trauma center startup.--There is established a trauma center startup grant program.

(1) The Legislature recognizes the need for a statewide, cohesive, uniform, and integrated trauma system, and the Legislature acknowledges that the state has been divided into trauma service areas. Each of the trauma service areas should have at least one trauma center; however, some trauma service areas do not have a trauma center because of the significant up-front investment of capital required for hospitals to develop the physical space, equipment, and qualified personnel necessary to provide quality trauma services.

(2) An acute care general hospital that has submitted a letter of intent and an application to become a trauma center pursuant to s. 395.4025 may apply to the department for a startup grant. The grant applicant must demonstrate that:

(a) There are currently no other trauma centers in the hospital's trauma service area as established under s. 395.402.

(b) There is not a trauma center within a 100-mile radius of the proposed trauma center.

(c) The hospital has received a local funding contribution as defined under s. 395.4001.

(d) The hospital has incurred startup costs in excess of the amount of grant funding requested.

(e) The hospital is pursuing the establishment of a residency program in internal medicine or emergency medicine.

(3) A hospital receiving startup grant funding that does not become a provisional trauma center within 24 months after submitting an application to become a trauma center must forfeit any state grant funds received pursuant to this section.

(4) A hospital that receives startup grant funding may not receive more than $500,000, must ensure that the startup grant funding is matched on a dollar-for-dollar basis with a local

funding contribution, and shall receive startup grant funding only one time.

Section 5. Section (4) of this act is effective subject to an appropriation in the General Appropriation Act.

Section 6. This act shall take effect July 1, 2006.

========== T I T L E A M E N D M E N T ==========

Remove the entire title and insert:

A bill to be entitled

An act relating to trauma services; amending s. 395.4001, F.S.; providing definitions; repealing s. 395.4035, F.S., to terminate the Trauma Services Trust Fund; amending s. 395.4036, F.S.; revising provisions relating to distribution of funds to trauma centers and use thereof; creating s. 395.41, F.S.; establishing a trauma center startup grant program; providing conditions for the receipt of a startup grant; providing limitations; making trauma startup grant program subject to an appropriation in the General Appropriations Act; providing an effective date.

## HOUSE OF REPRESENTATIVES STAFF ANALYSIS

**BILL #:** HB 819 CS Radiologist Assistants
**SPONSOR(S):** Grant
**TIED BILLS:** **IDEN./SIM. BILLS:** SB 1366

| REFERENCE | ACTION | ANALYST | STAFF DIRECTOR |
|---|---|---|---|
| 1) Health Care Regulation Committee | 10 Y, 0 N, w/CS | Hamrick | Mitchell |
| 2) Health Care Appropriations Committee | | Money | Massengale |
| 3) Health & Families Council | | | |
| 4) | | | |
| 5) | | | |

## SUMMARY ANALYSIS

Section 11.62, F.S., the Sunrise Act that establishes criteria for new regulation of professions, states that it is the intent of the Legislature that no profession or occupation be subject to regulation by the state unless the regulation is necessary to protect the public health, safety, or welfare from significant and discernible harm or damage; and no profession or occupation be regulated by the state in a manner that unnecessarily restricts entry into the practice of the profession or occupation.

House Bill 819 CS provides for the certification of a relatively new profession called a radiologist assistant. The radiologist assistant functions as a physician extender for a radiologist. Currently only three states regulate radiologist assistants: Montana, Tennessee and Mississippi. The bill incorporates radiologist assistants into the "Radiology Technologist Certification Act' (chapter 468, part VI, F.S.). The bill renames the act as the "Radiological Personnel Certification Act."

A "radiologist assistant" is a person, other than a licensed practitioner, who is qualified by education and certification as an advanced-level radiologic technologist, who works under the supervision of a radiologist to enhance patient care by assisting the radiologist in the medical imaging environment. A radiologist assistant may perform, under the supervision of a radiologist (who is a medical doctor), certain procedures such as arthograms, upper and lower gastrointestinal tract examinations, placements of feeding tubes, and central venous catheters.

The bill specifies that the scope of practice for a radiologist assistant must be adopted by rule and be consistent with the national scope of practice adopted by the American College of Radiology (ACR), the American Society of Radiologic Technologists (ASRT), and the American Registry of Radiologic Technologists (ARRT). The bill restricts the scope of practice of radiologist assistant such that they may not interpret images, make a diagnosis, or prescribe medications. A radiologist assistant must be under the "direct" supervision of a radiologist who must be present in the office suite and immediately available to furnish assistance and direction throughout a medical procedure. The bill provides for fees and educational requirements to include a clinical preceptorship. The bill adds a radiologist assistant to the Advisory Council on Radiation Protection.

According to the Department of Health, the fiscal impact to the department will be minimal since the fees to regulate the profession would cover their administrative costs.

The bill takes effect on July 1, 2006.

## FULL ANALYSIS

## I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

**Limited government and safeguard individual liberty**—The bill will allow a radiologist (who is a medical doctor) to use a radiologist assistant as a physician extender, which may allow increased access to radiologic services by consumers.

B. EFFECT OF PROPOSED CHANGES:

**Current Situation**

The State of Florida currently regulates several general types of individuals who use radiological techniques in health care: basic x-ray machine operators, general radiographers, radiologic technologists and radiologists. Current statute recognizes specializations within each of these categories. For example, a basic x-ray machine operator may specialize in podiatric medicine or a certified radiologic technologist may specialize in nuclear medicine.[1] These professions are not regulated by a board, but an advisory council makes recommendations to the Division of Medical Quality Assurance within the Department of Health concerning the requirements and qualifications for all the professions in the field of radiology.

A person may not use radiation or otherwise practice radiologic technology on a human being unless he or she possesses a license or is certified by the Department of Health. The term "radiation" encompasses x-rays and gamma rays, alpha and beta particles, high-speed electrons, neutrons, and other nuclear particles. If an individual uses radiation on another person and is not in compliance with s. 468.302, F.S., they may be charged with a second degree misdemeanor pursuant to s. 468.311, F.S.

The bill provides for the certification of radiologist assistants (RA). A radiologist assistant will act as a radiologist extender. The proponents for the legislation provided examples of other physician extenders such as anesthesiologist and nurse anesthetists. According to the proponents of the bill, only three states—Montana, Tennessee and Mississippi—have passed laws regulating RAs, while others are seeking legislation.

**Sunrise Act**

The proponents of this legislation did not submit a sunrise questionnaire for staff to review.

According to s. 11.62(3), F.S., of the Florida Sunrise Act, the Legislature is required to consider the following factors when determining whether to regulate a profession:

- **The unregulated practice of the profession will substantially harm or endanger the public health, safety, or welfare, and whether the potential for harm is recognizable and not remote.**

  Currently, an individual who is not certified or licensed by the Department of Health may not use radiation on a human being. A prerequisite for national certification as a radiologist assistant is that the individual be certified as a general radiographer (or radiologic technologist). Currently, if an individual performed the duties of a radiologist assistant in Florida they would be practicing out of the scope of their profession and subject to disciplinary charges. Since this is a new profession, not just to Florida, but across the nation, the potential harm or danger to the public is unknown. The duties outlined in the scope of practice of a radiologic assistant in the bill are currently performed by a licensed medical doctor.

[1] See s. 468.302, F.S.

- **The practice of the profession requires specialized skill or training, and whether that skill or training is readily measurable or quantifiable so that examination or training requirements reasonably assure initial and continuing professional ability.**

  Based on the information gathered by staff, the role of a radiologist assistant will require specialized skill and training. According to the American Society of Radiologic Technologists (ASRT) and the American Registry of Radiologic Technologists (ARRT) their training will be readily measurable or quantifiable.

- **The regulation will not unreasonably effect job creation or retention in the state, or place unreasonable restrictions on finding employment by individuals who practice or seek to practice the profession.**

  Since this is a new profession and limited schools in the United States offer the program, the impact on other professions such as the radiologic technologist or basic x-ray machine operator is difficult to project. However, the educational backgrounds for both of these professions is substantially different from the radiologist assistant who is required to have at least a bachelors degree. Radiologic technologists and x-ray operators may only have an associates degree or certificate of completion. If passed, this legislation may provide an avenue for individuals in the field to advance their knowledge and skill in the field if they return to school.

- **Whether the public is not, or can not, be effectively protected by other means.**

  Currently, the public is receiving the services of a radiologic assistant by a radiologist, who is a licensed medical doctor. Because of workforce shortages in the field of radiology, the provisions of the bill may increase assess to radiologic services.

- **Whether the overall cost-effectiveness and economic impact of the proposed regulation, including the indirect costs to consumers, is favorable.**

  The bill creates another tier of practitioner in the field of radiology. The services that are currently provided to consumers are performed by a medical doctor (a radiologist) or a technician (radiologic technologist or x-ray operator) who may have an associate's degree. The radiologist assistant (RA) must have at least a bachelor's degree. For this reason, a radiologist assistant may want to be paid at a higher rate than a radiologic technologist.

**The Effects of the Bill**

The bill provides for the certification of a new profession called a radiologist assistant. The radiologist assistant will function as a physician extender for a radiologist. A "radiologist assistant" is defined as a person, other than a licensed practitioner, who is qualified by education and certification as an advanced-level radiologic technologist who works under the supervision of a radiologist to enhance patient care by assisting the radiologist in the medical imaging environment.

The bill incorporates the radiologist assistant to the entire section that is called the "Radiology Technologist Certification Act' (chapter 468, part VI, F.S.). The bill renames the act as the "Radiological Personnel Certification Act." The bill provides a definition of "certificate holder" to mean any person who holds a certificate and is authorized to use radiation on human beings. This term is used through out the act in a manner that allows for the incorporation of radiologist assistants.

The bill provides that the scope of practice for a radiologist assistant must be adopted by rule and be consistent with the national scope of practice adopted by the American College of Radiology (ACR), the American Society of Radiologic Technologists (ASRT), and the American Registry of Radiologic Technologists (ARRT). The bill restricts the scope of practice of radiologist assistants such that they

may not interpret images, make a diagnosis, or prescribe medications or therapies. A radiologist assistant may not perform nuclear medicine or radiation therapy procedures unless they are certified and trained in those areas.

The bill provides that a radiologist assistant is supervised such that the radiologist (who is a medical doctor) must be present in the office suite and immediately available to furnish assistance and direction throughout a medical procedure. This does not require the radiologist to be in the room while the procedure is performed. The bill provides for fees and educational requirements to include a clinical preceptorship. The bill adds a radiologist assistant to the Advisory Council on Radiation Protection.

## BACKGROUND

### American Society of Radiologic Technologists (ASRT) Radiologist Assistant Certification Program

The concept of a radiologist extender was first explored in the early 1970s and revived in the mid-1990s. In early 2002, the American Society of Radiologic Technologists (ASRT) convened a panel to explore the concept of a physician extender in radiology. Representatives from the American College of Radiology (ACR), the American Society of Radiologic Technologists (ASRT, or the Society), the American Registry of Radiologic Technologists (ARRT, or the Registry), state licensing agencies, the National Society of Radiology Practitioner Assistants, and the industry produced a consensus document proposing the positions title and definition and addressing educational preparation, roles and responsibilities, level of supervision, and regulatory issues. Building on the panel's concept and consensus, the Registry developed certification standards. The radiologist assistant program incorporates educational, ethical and exam standards.

According to the Society, educational standards for a radiologist assistant are designed to address the didactic and clinical components of the field, as well as a national certification and registration in radiography. Clinical education is provided through a preceptorship with a radiologist. Radiologist assistant programs provide a baccalaureate degree or higher. In 2005, six universities offered radiologist assistant educational programs. An individual must be certified as a radiographer by the registry, as a prerequisite to enrollment in a radiologist assistant program. Graduates of a radiologist assistant program may sit for the radiologist assistant certification examination administered by the Registry.

### The Radiologist Assistant and National Scope of Practice Outlined by the ACR, ASRT and ARRT

A radiologist assistant works under the supervision of a radiologist to provide patient care as a radiologist extender in the diagnostic imaging environment. Radiologist assistants (RAs) have three major areas of responsibility.

First, they have a leading role in patient management and assessment. Duties in this area may include determining whether a patient has been appropriately prepared for a procedure, obtaining patient consent prior to beginning the procedure, answering questions from the patient and his or her family, and adapting exam protocols to improve diagnostic quality. The radiologist assistant is expected to serve as a patient advocate, ensuring that each patient receives quality care while in the radiology department or clinic.[2]

Second, the radiologist assistant performs selected radiology examinations and procedures under the supervision of a radiologist. A RA's responsibilities may include assisting radiologists with invasive procedures such as arthograms, upper and lower gastrointestinal tract examinations, urinary tract examinations, lymphanogiograms, performing fluoroscopy for noninvasive procedures under direct supervision of the radiologist, placement of nasoenteric and oroenteric feeding tubes, and performing

[2] American Society of Radiologic Technologists. The Radiologist Assistant. http://www.asrt.org/content/RTs/SpecialtySpecific/RadiologistAssistant/Radiologist_Assistant.aspx (March 25, 2006).

selected peripheral venous diagnostic procedures such as venograms, paracentesis, thoracentesis or the insertion of central venus catheters.[3]

Third, the radiologist assistant may be responsible for evaluating image quality, making initial image observations and forwarding those observations to the supervising radiologist. The supervising radiologist remains responsible for providing a final written report, an interpretation or a diagnosis.[4]

**Current Professions in the Field of Radiology that are Regulated in Florida**

Basic X-ray Machine Operator is Certified

A basic x-ray machine operator may perform general diagnostic radiographic and general fluoroscopic procedures under the direct supervision of a licensed practitioner (doctor, podiatrist, or chiropractor), excluding radiation therapy and nuclear medicine. They are limited to the locations they may work such that they are not allowed to work in a hospital with less than 150 beds or a walk-in emergency center.[5]

Radiologic Technologist is trained to Operate Equipment and is Certified

A radiologic technologist is trained to operate radiographic equipment to produce images. The radiologic technologist may explain the imaging procedure to the patient and assist in positioning the patient for imaging specific areas of the patient's body as prescribed by the referring physician.[6] A radiologic technologist may use radiation on human beings under the specific direction and general supervision of a licensed practitioner as defined in s. 468.301(14), F.S.

A Radiologist is a Licensed Medical Doctor

A radiologist is a licensed medical or osteopathic physician trained to diagnose diseases by obtaining and interpreting medical images through the use of imaging techniques such as X-rays, ultrasound, computed tomography, and magnetic resonance imaging. A radiologist must have graduated from an accredited medical school, passed a national licensing examination, and completed a residency of at least four years. Such health care practitioners are usually board-certified to practice in the field of radiology by the American Board of Radiology or the American Osteopathic Board of Radiology.

**Advisory Council on Radiation Protection**

In Florida, there is an Advisory Council on Radiation Protection, not a board, that oversees the practice of radiology. The council consists of 15 specified professionals and consumers appointed by the Secretary of Health:

- Certified radiologic technologist-radiographer.
- Certified radiologic technologist-nuclear medicine.
- Certified radiologic technologist-therapy.
- Basic X-ray machine operator or a licensed practitioner who employs such an operator.
- Board-certified radiologist.
- Board-certified nuclear medicine physician.
- Certified health physicist.
- Representative from the administration of a hospital affiliated with a radiologic technology educational program.
- An expert in environmental radiation matters.
- Chiropractic radiologist, a board-certified podiatric physician.
- Board-certified radiological physicist.
- Board-certified therapeutic radiologist or board-certified radiation oncologist.
- Two persons, neither of whom has ever been certified as a radiologic technologist or been a member of any closely related profession.

[3] Ibid.
[4] Ibid.
[5] See s. 468.302(3), F.S.
[6] Ibid.

C. SECTION DIRECTORY:

**Section 1.** Amends s. 468.3001, F.S., redesignating part IV of chapter 468 as the "Radiological Personnel Certification Act."

**Section 2.** Amends s. 468.301, F.S., providing a definition for certificate holder, radiologist and radiologist assistant.

**Section 3.** Amends s. 468.302, F.S., providing identification and duties of a certified radiologist assistant; rulemaking authority to the Department of Health; and specify limitation on the duties of a radiologist assistant.

**Section 4.** Amends s. 468.304, F.S., providing certification criteria for an applicant seeking a radiologist assistant certificate.

**Section 5.** Amends s. 468.306, F.S., exempting radiologist assistants from examination requirements as long as they possess a current certification granted by the American Registry of Radiologic Technologists.

**Section 6.** Amends s. 468.3065, F.S., extending licensure by endorsement provisions to radiologist assistants if they remit a fee and possess a current certification granted by the American Registry of Radiologic Technologists.

**Sections 7 through 12** to amend s. 468.307, 468.309, 468.3095, 468.3101, 468.311, and 468.3115 F.S., including radiologist assistants in provisions that deal with certificate display, certificate renewal, change of certificate status, grounds for disciplinary action, violations, penalties, and injunctive relief.

**Section 13.** Amends s. 468.314, F.S., providing for an additional member to the Advisory Council on Radiation Protection.

**Section 14.** Provides that the bill will take effect on July 1, 2006.

## II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   See Fiscal Comments.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Radiologist assistant applicants for certification by endorsement must pay a nonrefundable application fee no greater than $50.

D. FISCAL COMMENTS:

According to the Department of Health, the fiscal impact to the department to enforce regulatory provisions relating to the certification of radiologist assistants will be minimal since the fees to regulate the profession will cover their administrative costs. According to the Bureau of Radiation Control within DOH, only about 10 radiologist assistants become certified in the nation on an annually. This number may increase to 20 if the exam is offered biannually.

## III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not require counties or municipalities to spend funds or take action requiring the expenditure of funds. This bill does not reduce the percentage of state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill provides the Department of Health with adequate rule-making authority to implement the provisions provided for in the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

## IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

On March 28, 2006, the Health Care Regulation Committee adopted a strike-all amendment offered by the bill's sponsor. The Committee Substitute differs from the original bill as filed in that it:

- Incorporates the radiologist assistant to the entire section of statute that is called the "Radiology Technologist Certification Act' (chapter 468, part VI, F.S.).
- Renames the act as the "Radiological Personnel Certification Act."
- Provides a definition of "certificateholder" to mean any person who holds a certificate and is authorized to use radiation on human beings.
- The term "certificateholder" and "radiologist assistants" is used through out the act to incorporate radiologist assistants into all of the provisions within the practice act.

The bill, as amended, was reported favorably as a committee substitute. This analysis is drafted to the committee substitute.

CHAMBER ACTION

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The Health Care Regulation Committee recommends the following:

**Council/Committee Substitute**

Remove the entire bill and insert:

A bill to be entitled

An act relating to radiologist assistants; amending s. 468.3001, F.S.; redesignating part IV of ch. 468, F.S., as the "Radiological Personnel Certification Act"; amending s. 468.301, F.S.; providing definitions; amending s. 468.302, F.S.; providing for identification and duties of a radiologist assistant; providing for rulemaking by the Department of Health; providing limitations on duties a radiologist assistant may perform; amending s. 468.304, F.S.; providing conditions for qualification for a radiologist assistant's certificate; amending s. 468.306, F.S.; specifying the applicants required to pass a certification examination; requiring the department to accept certain demonstrations by an applicant for a certification to practice as a radiologist assistant in lieu of any examination requirement; amending s. 468.3065, F.S.; authorizing the Department of Health to issue certificates by endorsement to certain radiologist assistants; providing for a fee; amending ss. 468.307,

468.309, 468.3095, 468.3101, 468.311, and 468.3115, F.S.; including radiologist assistants in provisions applicable to radiologic technologists with respect to requirements for certificate display, certificate renewal, change of certificate status, grounds for disciplinary action, violations, penalties, and injunctive relief; amending s. 468.314, F.S.; adding a certified radiologist assistant to the membership of the Advisory Council on Radiation Protection; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 468.3001, Florida Statutes, is amended to read:

468.3001 Short title.--This part ~~shall be known and~~ may be cited as the "Radiological Personnel ~~Radiologic Technologist~~ Certification Act."

Section 2. Present subsections (4) through (14) of section 468.301, Florida Statutes, are renumbered as subsections (5) through (15), respectively, present subsection (15) is renumbered as subsection (18), new subsections (4), (16), and (17) are added to that section, and present subsection (14) of that section is amended, to read:

468.301 Definitions.--As used in this part, the term:

(4) "Certificateholder" means any person who holds a certificate under this part that authorizes that person to use radiation on human beings.

(15) ~~(14)~~ "Radiologic technologist" means a person, other than a licensed practitioner, who is qualified by education, training, or experience, as more specifically defined in s. 468.302(3)(d)-(g) ~~s. 468.302~~, to use radiation on human beings under the specific direction and general supervision of a licensed practitioner in each particular case.

(16) "Radiologist" means a physician specializing in radiology certified by or eligible for certification by the American Board of Radiology or the American Osteopathic Board of Radiology, the British Royal College of Radiology, or the Canadian College of Physicians and Surgeons.

(17) "Radiologist assistant" means a person, other than a licensed practitioner, who is qualified by education and certification, as set forth in s. 468.304, as an advanced-level radiologic technologist who works under the supervision of a radiologist to enhance patient care by assisting the radiologist in the medical imaging environment.

Section 3. Subsections (1), (5), and (6) of section 468.302, Florida Statutes, are amended, paragraph (g) is added to subsection (2) of that section, and paragraph (h) is added to subsection (3) of that section, to read:

468.302 Use of radiation; identification of certified persons; limitations; exceptions.--

(1) Except as provided in this section, a person may not use radiation or otherwise practice radiologic technology or any of the duties of a radiologist assistant on a human being unless he or she:

(a) Is a licensed practitioner; ~~or~~

(b) Is the holder of a certificate, as provided in this part, and is operating under the direct supervision or general supervision of a licensed practitioner in each particular case; or.

(c) Is the holder of a radiologist assistant certificate, as provided in this part, and is operating under the supervision of a radiologist, as specified in paragraph (3)(h).

(2)

(g) A person holding a certificate as a radiologist assistant may use the title "Certified Radiologist Assistant" or the letters "CRA" after his or her name.

No other person is entitled to so use a title or letters contained in this subsection or to hold himself or herself out in any way, whether orally or in writing, expressly or by implication, as being so certified.

(3)

(h) A person holding a certificate as a radiologist assistant may:

1. Perform specific duties allowed for a radiologist assistant as defined by the department by rule. The rule must be consistent with guidelines adopted by the American College of Radiology, the American Society of Radiologic Technologists, and the American Registry of Radiologic Technologists, with the level of supervision required by such guidelines.

2. Not perform nuclear medicine or radiation therapy procedures unless currently certified and trained to perform those duties under the person's nuclear medicine technologist or

radiation therapy technologist certificate, interpret images, make diagnoses, or prescribe medications or therapies.

(5) Nothing contained in this part relating to radiologic technology or a radiologist assistant shall be construed to limit, enlarge, or affect in any respect the practice by duly licensed practitioners of their respective professions.

(6) Requirement for certification does not apply to:

(a) A hospital resident who is not a licensed practitioner in this state or a student enrolled in and attending a school or college of medicine, osteopathic medicine, chiropody, podiatric medicine, or chiropractic medicine or a radiologic technology educational program or radiologist assistant educational program and who applies radiation to a human being while under the direct supervision of a licensed practitioner.

(b) A person who is engaged in performing the duties of a radiologic technologist or of a radiologist assistant in his or her employment by a governmental agency of the United States.

(c) A person who is trained and skilled in cardiopulmonary technology and who provides cardiopulmonary technology services at the direction, and under the direct supervision, of a licensed practitioner.

Section 4. Paragraph (e) of subsection (3) of section 468.304, Florida Statutes, is amended to read:

468.304 Certification.--The department shall certify any applicant who meets the following criteria:

(3) Submits satisfactory evidence, verified by oath or affirmation, that she or he:

(e)1. Has successfully completed an educational program, which program may be established in a hospital licensed pursuant to chapter 395 or in an accredited postsecondary academic institution which is subject to approval by the department as maintaining a satisfactory standard; or

2.a. With respect to an applicant for a basic X-ray machine operator's certificate, has completed a course of study approved by the department with appropriate study material provided the applicant by the department;

b. With respect to an applicant for a basic X-ray machine operator-podiatric medicine certificate, has completed a course of study approved by the department, provided that such course of study shall be limited to that information necessary to perform radiographic procedures within the scope of practice of a podiatric physician licensed pursuant to chapter 461;

c. With respect only to an applicant for a general radiographer's certificate who is a basic X-ray machine operator certificateholder, has completed an educational program or a 2-year training program that takes into account the types of procedures and level of supervision usually and customarily practiced in a hospital, which educational or training program complies with the rules of the department; ~~or~~

d. With respect only to an applicant for a nuclear medicine technologist's certificate who is a general radiographer certificateholder, has completed an educational program or a 2-year training program that takes into account the types of procedures and level of supervision usually and

customarily practiced in a hospital, which educational or training program complies with the rules of the department; or.

e. With respect to an applicant for a radiologist assistant's certificate who demonstrates to the department that he or she holds a current certificate or registration as a radiologist assistant granted by the American Registry of Radiologic Technologists.

The department may not certify any applicant who has committed an offense that would constitute a violation of any of the provisions of s. 468.3101 or the rules adopted thereunder if the applicant had been certified by the department at the time of the offense. No application for a limited computed tomography certificate shall be accepted. All persons holding valid computed tomography certificates as of October 1, 1984, are subject to the provisions of s. 468.309.

Section 5. Section 468.306, Florida Statutes, is amended to read:

468.306 Examinations.--All applicants for certification as a radiologic technologist, basic X-ray machine operator, or basic X-ray machine operator-podiatric medicine, except those certified pursuant to s. 468.3065, shall be required to pass an examination. In lieu of an examination for a radiologist assistant certificate, the department shall accept a demonstration by the applicant for such a certificate that he or she holds a current certificate or registration as a radiologist assistant granted by the American Registry of Radiologic Technologists. The department may ~~is authorized to~~ develop or

use examinations for each type of certificate. The department may require an applicant who does not pass an examination after five attempts to complete additional remedial education, as specified by rule of the department, before admitting the applicant to subsequent examinations.

(1) The department may ~~shall have the authority to~~ contract with organizations that develop such test examinations. Examinations may be administered by the department or the contracting organization.

(2) Examinations shall be given for each type of certificate at least twice a year at such times and places as the department may determine to be advantageous for applicants.

(3) All examinations shall be written and include positioning, technique, and radiation protection. The department shall either pass or fail each applicant on the basis of his or her final grade. The examination for a basic X-ray machine operator shall include basic positioning and basic techniques directly related to the skills necessary to safely operate radiographic equipment.

(4) A nonrefundable fee not to exceed $75 plus the actual per-applicant cost for purchasing the examination from a national organization shall be charged for any subsequent examination.

Section 6. Section 468.3065, Florida Statutes, is amended to read:

468.3065 Certification by endorsement.--

(1) The department may issue a certificate by endorsement to practice as a radiologist assistant to an applicant who, upon

applying to the department and remitting a nonrefundable fee not to exceed $50, demonstrates to the department that he or she holds a current certificate or registration as a radiologist assistant granted by the American Registry of Radiologic Technologists.

(2) The department may issue a certificate by endorsement to practice radiologic technology to an applicant who, upon applying to the department and remitting a nonrefundable fee not to exceed $50, demonstrates to the department that he or she holds a current certificate, license, or registration to practice radiologic technology, provided that the requirements for such certificate, license, or registration are deemed by the department to be substantially equivalent to those established under this part and rules adopted under this part.

Section 7. Subsection (3) of section 468.307, Florida Statutes, is amended to read:

468.307 Certificate; issuance; display.--

(3) Every employer of certificateholders ~~radiologic technologists~~ shall display the certificates of all of such employees in a place accessible to view.

Section 8. Paragraph (a) of subsection (1) and subsections (4), (5), (6), and (7) of section 468.309, Florida Statutes, are amended to read:

468.309 Certificate; duration; renewal; reversion to inactive status; members of Armed Forces and spouses.--

(1)(a) A ~~radiologic technologist's~~ certificate issued in accordance with this part expires as specified in rules adopted by the department which establish a procedure for the biennial

renewal of certificates. A certificate shall be renewed by the department for a period of 2 years upon payment of a renewal fee in an amount not to exceed $75 and upon submission of a renewal application containing such information as the department deems necessary to show that the applicant for renewal is a certificateholder ~~radiologic technologist~~ in good standing and has completed any continuing education requirements that the department establishes.

(4) Any certificate that is not renewed by its expiration date shall automatically be placed in an expired status, and the certificateholder may not practice radiologic technology or perform the duties of a radiologist assistant until the certificate has been reactivated.

(5) A certificateholder in good standing remains in good standing when he or she becomes a member of the Armed Forces of the United States on active duty without paying renewal fees or accruing continuing education credits as long as he or she is a member of the Armed Forces on active duty and for a period of 6 months after discharge from active duty, if he or she is not engaged in practicing radiologic technology or performing the duties of a radiologist assistant in the private sector for profit. The certificateholder must pay a renewal fee and complete continuing education not to exceed 12 classroom hours to renew the certificate.

(6) A certificateholder who is in good standing remains in good standing if he or she is absent from the state because of his or her spouse's active duty with the Armed Forces of the United States. The certificateholder remains in good standing

without paying renewal fees or completing continuing education as long as his or her spouse is a member of the Armed Forces on active duty and for a period of 6 months after the spouse's discharge from active duty, if the certificateholder is not engaged in practicing radiologic technology or performing the duties of a radiologist assistant in the private sector for profit. The certificateholder must pay a renewal fee and complete continuing education not to exceed 12 classroom hours to renew the certificate.

(7) A certificateholder may resign his or her certification by submitting to the department a written, notarized resignation on a form specified by the department. The resignation automatically becomes effective upon the department's receipt of the resignation form, at which time the certificateholder's certification automatically becomes null and void and may not be reactivated or renewed or used to practice radiologic technology or to perform the duties of a radiologist assistant. A certificateholder who has resigned may become certified again only by reapplying to the department for certification as a new applicant and meeting the certification requirements pursuant to s. 468.304 or s. 468.3065. Any disciplinary action that had been imposed on the certificateholder prior to his or her resignation shall be tolled until he or she again becomes certified. Any disciplinary action proposed at the time of the certificateholder's resignation shall be tolled until he or she again becomes certified.

Section 9. Paragraphs (a) and (c) of subsection (2) of section 468.3095, Florida Statutes, are amended to read:

468.3095 Inactive status; reactivation; automatic suspension; reinstatement.--

(2)(a) A certificate that has been expired for less than 10 years may be reactivated upon payment of the biennial renewal fee and a late renewal fee, not to exceed $100, and submission of a reactivation application containing any information that the department deems necessary to show that the applicant is a certificateholder ~~radiologic technologist~~ in good standing and has met the requirements for continuing education. The department shall prescribe, by rule, continuing education requirements as a condition of reactivating a certificate. The continuing education requirements for reactivating a certificate may not exceed 10 classroom hours for each year the certificate was expired and may not exceed 100 classroom hours for all years in which the certificate was expired.

(c) A certificate that has been inactive or expired for 10 years or more automatically becomes null and void and may not be reactivated, renewed, or used to practice radiologic technology or to perform the duties of a radiologist assistant. A certificateholder whose certificate has become null and void may become certified again only by reapplying to the department as a new applicant and meeting the requirements of s. 468.304 or s. 468.3065.

Section 10. Subsections (1), (2), (3), and (5) of section 468.3101, Florida Statutes, are amended to read:

468.3101 Disciplinary grounds and actions.--

(1) The department may make or require to be made any investigations, inspections, evaluations, and tests, and require the submission of any documents and statements, which it considers necessary to determine whether a violation of this part has occurred. The following acts shall be grounds for disciplinary action as set forth in this section:

(a) Procuring, attempting to procure, or renewing a certificate ~~to practice radiologic technology~~ by bribery, by fraudulent misrepresentation, or through an error of the department.

(b) Having a voluntary or mandatory certificate to practice radiologic technology or to perform the duties of a radiologist assistant revoked, suspended, or otherwise acted against, including being denied certification, by a national organization; by a specialty board recognized by the department; or by a certification authority of another state, territory, or country.

(c) Being convicted or found guilty, regardless of adjudication, in any jurisdiction of a crime that directly relates to the practice of radiologic technology or to the performance of the duties of a radiologist assistant, or to the ability to practice radiologic technology or the ability to perform the duties of a radiologist assistant. Pleading nolo contendere shall be considered a conviction for the purpose of this provision.

(d) Being convicted or found guilty, regardless of adjudication, in any jurisdiction of a crime against a person.

Pleading nolo contendere shall be considered a conviction for the purposes of this provision.

(e) Making or filing a false report or record that the certificateholder knows to be false, intentionally or negligently failing to file a report or record required by state or federal law, or willfully impeding or obstructing such filing or inducing another to do so. Such reports or records include only those reports or records which are signed in the capacity of the certificateholder ~~as a radiologic technologist~~.

(f) Engaging in unprofessional conduct, which includes, but is not limited to, any departure from, or the failure to conform to, the standards of practice of radiologic technology or the standards of practice for radiologist assistants as established by the department, in which case actual injury need not be established.

(g) Being unable to practice radiologic technology or to perform the duties of a radiologist assistant with reasonable skill and safety to patients by reason of illness or use of alcohol, drugs, narcotics, chemicals, or other materials or as a result of any mental or physical condition. A certificateholder ~~radiologic technologist~~ affected under this paragraph shall, at reasonable intervals, be afforded an opportunity to demonstrate that he or she can resume the competent practice of his or her certified profession ~~radiologic technology~~ with reasonable skill and safety.

(h) Failing to report to the department any person who the certificateholder knows is in violation of this part or of the rules of the department.

(i) Violating any provision of this part, any rule of the department, or any lawful order of the department previously entered in a disciplinary proceeding or failing to comply with a lawfully issued subpoena of the department.

(j) Employing, for the purpose of applying ionizing radiation or otherwise practicing radiologic technology or performing the duties of a radiologist assistant on a human being, any individual who is not certified under the provisions of this part.

(k) Testing positive for any drug, as defined in s. 112.0455, on any confirmed preemployment or employer-required drug screening when the certificateholder ~~radiologic technologist~~ does not have a lawful prescription and legitimate medical reason for using such drug.

(l) Failing to report to the department in writing within 30 days after the certificateholder has had a voluntary or mandatory certificate to practice radiologic technology or to perform the duties of a radiologist assistant revoked, suspended, or otherwise acted against, including being denied certification, by a national organization, by a specialty board recognized by the department, or by a certification authority of another state, territory, or country.

(m) Having been found guilty of, regardless of adjudication, or pleading guilty or nolo contendere to, any offense prohibited under s. 435.03 or under any similar statute of another jurisdiction.

(n) Failing to comply with the recommendations of the department's impaired practitioner program for treatment,

evaluation, or monitoring. A letter from the director of the impaired practitioner program that the certificateholder is not in compliance shall be considered conclusive proof under this part.

(2) If the department finds any person or firm guilty of any of the grounds set forth in subsection (1), it may enter an order imposing one or more of the following penalties:

(a) Refusal to approve an application for certification.

(b) Revocation or suspension of a certificate.

(c) Imposition of an administrative fine not to exceed $1,000 for each count or separate offense.

(d) Issuance of a reprimand.

(e) Placement of the certificateholder ~~radiologic technologist~~ on probation for such period of time and subject to such conditions as the department may specify, including requiring the certificateholder ~~radiologic technologist~~ to submit to treatment, to undertake further relevant education or training, to take an examination, or to work under the supervision of a licensed practitioner.

(3) The department shall not reinstate a person's ~~the~~ certificate ~~of a radiologic technologist~~, or cause a certificate to be issued to a person it has deemed unqualified, until such time as the department is satisfied that such person has complied with all the terms and conditions set forth in the final order and is capable of safely engaging in the practice of his or her certified profession ~~radiologic technology~~.

(5) A final disciplinary action taken against a certificateholder ~~radiologic technologist~~ in another

jurisdiction, whether voluntary or mandatory, shall be considered conclusive proof of grounds for a disciplinary proceeding under this part.

Section 11. Section 468.311, Florida Statutes, is amended to read:

468.311 Violations; penalties.--Each of the following acts constitutes a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083:

(1) Practicing radiologic technology or performing the duties of a radiologist assistant without holding an active certificate to do so.

(2) Using or attempting to use a certificate which has been suspended or revoked.

(3) The willful practice of radiologic technology or the willful performance of the duties of a radiologist assistant by a student ~~radiologic technologist~~ without a direct supervisor being present.

(4) Knowingly allowing a student ~~radiologic technologist~~ to practice radiologic technology or perform the duties of a radiologist assistant without a direct supervisor being present.

(5) Obtaining or attempting to obtain a certificate under this part through bribery or fraudulent misrepresentation.

(6) Using any ~~the~~ name or title specified in s. 468.302(2) ~~"Certified Radiologic Technologist"~~ or any other name or title which implies that a person is certified to practice radiologic technology or to perform the duties of a radiologist assistant, unless such person is duly certified as provided in this part.

(7) Knowingly concealing information relating to the enforcement of this part or rules adopted pursuant to this part.

(8) Employing, for the purpose of applying ionizing radiation to, or otherwise practicing radiologic technology or any of the duties of a radiologist assistant on, any human being, any individual who is not certified under the provisions of this part.

Section 12. Section 468.3115, Florida Statutes, is amended to read:

468.3115 Injunctive relief.--The practice of radiologic technology or the performance of the duties of a radiologist assistant in violation of this part, or the performance of any act prohibited in this part, is declared a nuisance inimical to the public health, safety, and welfare of this state. In addition to other remedies provided in this part, the department, or any state attorney in the name of the people of this state, may bring an action for an injunction to restrain such violation until compliance with the provisions of this part and the rules adopted pursuant to this part has been demonstrated to the satisfaction of the department.

Section 13. Subsections (1), (2), and (5) of section 468.314, Florida Statutes, are amended to read:

468.314 Advisory Council on Radiation Protection; appointment; terms; powers; duties.--

(1) The Advisory Council on Radiation Protection is created within the Department of Health and shall consist of 16 ~~15~~ persons to be appointed by the secretary for 3-year terms.

(2) The council shall be comprised of:

(a) A certified radiologic technologist-radiographer.

(b) A certified radiologic technologist-nuclear medicine.

(c) A certified radiologic technologist-therapy.

(d) A basic X-ray machine operator or a licensed practitioner who employs such an operator.

(e) A board-certified radiologist.

(f) A board-certified nuclear medicine physician.

(g) A certified health physicist.

(h) A certified radiologist assistant.

(i) ~~(h)~~ A representative from the administration of a hospital affiliated with a radiologic technology educational program.

(j) ~~(i)~~ An expert in environmental radiation matters.

(k) ~~(j)~~ A chiropractic radiologist.

(l) ~~(k)~~ A board-certified podiatric physician.

(m) ~~(l)~~ A board-certified radiological physicist.

(n) ~~(m)~~ A board-certified therapeutic radiologist or board-certified radiation oncologist.

(o) ~~(n)~~ Two persons, neither of whom has ever been certified pursuant to this part ~~as a radiologic technologist~~ or been a member of any closely related profession.

(5)(a) The council may recommend to the department examination procedures for applicants and minimum requirements for qualification of applicants.

(b) The council shall:

1. Recommend to the department a code of ethics for the certificateholder's practice of his or her certified profession ~~radiologic technology~~.

2. Make recommendations for the improvement of continuing education courses.

3. Make recommendations to the department on matters relating to the practice of radiologic technology, the performance of the duties of a radiologist assistant, and radiation protection.

4. Study the utilization of medical imaging and nonionizing radiation, such as nuclear magnetic resonance or similarly related technology, and make recommendations to the department on the personnel appropriate to conduct such procedures and the minimum qualifications for such personnel.

Section 14. This act shall take effect July 1, 2006.

## HOUSE OF REPRESENTATIVES STAFF ANALYSIS

**BILL #:** HB 1033 CS Child Abuse
**SPONSOR(S):** Vana
**TIED BILLS:** None. **IDEN./SIM. BILLS:** SB 2360

| REFERENCE | ACTION | ANALYST | STAFF DIRECTOR |
|---|---|---|---|
| 1) Future of Florida's Families Committee | 6 Y, 0 N, w/CS | Davis | Collins |
| 2) Health Care Appropriations Committee | | Ekholm | Massengale |
| 3) Health & Families Council | | | |
| 4) | | | |
| 5) | | | |

## SUMMARY ANALYSIS

House Bill 1033 CS requires that all Department of Children and Family Services (DCF) or community-based care employees working as child abuse professionals or anyone employed in the occupational categories defined as a "mandated reporter" by s. 39.201, F.S., (such as teachers, social workers, law enforcement and judges) must complete a 1-hour continuing education course on child abuse each year.

There is no significant fiscal impact on state government; the fiscal impact on the private sector depends on whether this course would be subsumed by current continuing education requirements.

The bill shall take effect on July 1, 2006.

## FULL ANALYSIS

## I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

**Provide Limited Government**—The bill requires DCF employees and mandatory reporters to complete a 1-hour continuing education course on child abuse each year.

B. EFFECT OF PROPOSED CHANGES:

**Background**

Chapter 39, F.S., mandates that any person who knows, or has reasonable cause to suspect, that a child is abused, neglected or abandoned by a parent, legal custodian, caregiver or other person responsible for the child's welfare shall immediately report such knowledge or suspicion to the Florida Abuse Hotline of the Department of Children and Family Services (DCF).

The department is also responsible, as mandated in chapter 39, F.S., for providing comprehensive protective services for abused, neglected and abandoned children in Florida by requiring that reports of each abused, neglected, or abandoned child be made to the Florida Abuse Hotline. The department is committed to working in partnership with local communities to ensure the safety, well-being and self-sufficiency for the people it serves. Law enforcement takes the lead in all criminal investigations and prosecution.

Departmental or Community-Based Care Staff:

Section 402.731, F.S., authorizes the department to create certification programs for its employees and service providers to ensure that only qualified employees and service providers provide client services. The department is authorized to develop rules that contain qualifications for certification, including training and testing requirements, continuing education requirements for ongoing certification, and decertification procedures to be used to determine when an individual no longer meets the qualifications to work as a child abuse professional.

Mandatory Reporters:

While statutory language exists authorizing the creation of continuing education requirements for ongoing certification of departmental and community-based care personnel, no such language currently exists for the "at-large" group of occupational classes that are defined as "mandated reporters" in s. 39.201, F.S.

**Effect**

The bill requires that all departmental or community-based care employees working as child abuse professionals or anyone employed in the occupational categories defined as a "mandated reporter" by s. 39.201, F.S., (such as teachers, social workers, law enforcement and judges) must complete a 1-hour continuing education course on child abuse each year. However, physicians, osteopathic physicians, medical examiners, chiropractic physicians, nurses, or hospital personnel engaged in the admission, examination, care or treatment of persons are excluded from this requirement.

C. SECTION DIRECTORY:

**Section 1.** Amends s. 39.001, F.S., requiring all Department of Children and Family Services employees and persons in specified occupation categories assigned to report, manage, or

supervise cases of child abuse, abandonment, and neglect to annually complete a continuing education course.

**Section 2.** Amends s. 39.201, F.S., requiring certain mandatory reporters of child abuse, abandonment, or neglect who are licensed or regulated by the state annually to complete a continuing education course. Provides exceptions to this requirement.

**Section 3.** Provides an effective date of July 1, 2006.

## II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

**Community-based Care Staff:**

Community-based care personnel training costs for child abuse professionals are currently funded through the Child Welfare Training Trust Funds (Title IV-E). There will be no additional fiscal impact.

**Mandatory Reporters:**

According to DCF, a critical determinant in projecting fiscal impact, as mentioned earlier, depends upon whether or not this course would be an "add-on" or subsumed by the current continuing education requirements for each professional category. The fiscal impact could be very limited if the child abuse course counted towards existing continuing education requirements for the occupational categories defined as mandatory reporters. It could be significant if professional accreditation groups would require this over and above their current requirements.

D. FISCAL COMMENTS:

None

## III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

The bill does not require counties or municipalities to spend funds or to take an action requiring the expenditure of funds. The bill does not reduce the percentage of a state tax shared with counties or municipalities. The bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The department has sufficient rulemaking authority to carry out the provisions of this bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

According to the Department of Children and Family Services:

**Departmental or Community-based Care Staff:**

Administrative Rule and operating procedures are currently being developed with the anticipation that the child welfare certification process will far exceed this bill's requirement for continuing education courses by professionals in this field. Whereas, this bill proposes one hour per year, the standard expected to be set will more likely require 15 hours of continuing education courses per year. Current ongoing continuing education requirements already exceed guidelines proposed by current bill and training costs are covered for caseworkers and supervisors through Child Welfare Training Trust Funds (Title IV-E).

**Mandatory Reporters:**

Most, if not all, of the occupational categories falling under the "mandated reporter" designation also have continuing education requirements as part of their re-licensure process. What is not known is if any of these occupational categories presently require a course on child abuse issues, this means many "mandated reporters" may already be meeting or exceeding the standards proposed by this bill. The bill does not describe a "tracking mechanism" regarding compliance with the new requirement. It is unclear if the department is expected to provide this oversight and/or develop a 1-hour continuing education course to help mandatory reporters satisfy this requirement.

## IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

On April 4, 2006, the Future of Florida's Families Committee adopted a Committee Substitute to HB 1033. The only change from the original bill is that certain mandated reporters are excluded from the 1-hour continuing education requirement. The bill analysis reflects this change.

CHAMBER ACTION

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The Future of Florida's Families Committee recommends the following:

**Council/Committee Substitute**

Remove the entire bill and insert:

A bill to be entitled

An act relating to child abuse; amending ss. 39.001 and 39.201, F.S.; requiring Department of Children and Family Services employees and persons in specified occupation categories assigned to report, manage, or supervise cases of child abuse, abandonment, and neglect to annually complete a continuing education course; providing exceptions; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Paragraph (e) of subsection (2) of section 39.001, Florida Statutes, is amended to read:

39.001 Purposes and intent; personnel standards and screening.--

(2) DEPARTMENT CONTRACTS.--The department may contract with the Federal Government, other state departments and agencies, county and municipal governments and agencies, public

and private agencies, and private individuals and corporations in carrying out the purposes of, and the responsibilities established in, this chapter.

(e) The department shall develop and implement a written and performance-based testing and evaluation program to ensure measurable competencies of all employees assigned to report, manage, or supervise cases of child abuse, abandonment, and neglect. All employees assigned to report, manage, or supervise cases of child abuse, abandonment, and neglect shall complete a 1-hour continuing education course on child abuse each year.

Section 2. Paragraph (b) of subsection (1) of section 39.201, Florida Statutes, is amended to read:

39.201 Mandatory reports of child abuse, abandonment, or neglect; mandatory reports of death; central abuse hotline.--

(1)

(b) Reporters licensed or regulated by the state and their employees who are mandatory reporters are required to complete a 1-hour continuing education course on child abuse each year, except for reporters in subparagraphs 1. and 2. Reporters in the following occupation categories are required to provide their names to the hotline staff:

1. Physician, osteopathic physician, medical examiner, chiropractic physician, nurse, or hospital personnel engaged in the admission, examination, care, or treatment of persons;

2. Health or mental health professional other than one listed in subparagraph 1.;

3. Practitioner who relies solely on spiritual means for healing;

4. School teacher or other school official or personnel;

5. Social worker, day care center worker, or other professional child care, foster care, residential, or institutional worker;

6. Law enforcement officer; or

7. Judge.

The names of reporters shall be entered into the record of the report, but shall be held confidential and exempt as provided in s. 39.202.

Section 3. This act shall take effect July 1, 2006.

# HOUSE OF REPRESENTATIVES STAFF ANALYSIS

**BILL #:** HB 1093 CS Physicians
**SPONSOR(S):** Altman and others
**TIED BILLS:** **IDEN./SIM. BILLS:** SB 1410

| REFERENCE | ACTION | ANALYST | STAFF DIRECTOR |
|---|---|---|---|
| 1) Health Care Regulation Committee | 8 Y, 0 N, w/CS | Hamrick | Mitchell |
| 2) Health Care Appropriations Committee | | Money | Massengale |
| 3) Health & Families Council | | | |
| 4) | | | |
| 5) | | | |

## SUMMARY ANALYSIS

House Bill 1093 CS requires the Division of Health Access and Tobacco within the Department of Health to monitor, evaluate and report on the supply, distribution and specialty of allopathic and osteopathic physicians in Florida. The bill requires the division to use data that is available from public and private sources.

The bill provides an option for physicians seeking licensure to:

- Submit their core credentials to the Federation Credentials Verifications Services of the Federation of State Medical Boards and submit their Physician Information Profile originating from the Federation to the Department of Health or
- Submit their core credentials directly to the Department of Health.

The federation verifies the submitted information and certifies it as a life-long primary source document from which a physician profile may be created and sent to employers, hospitals and the Board of Medicine, which then may evaluate an individual's eligibility for licensure.

According to the Department of Health, the cost to implement the provisions of the bill will be $161,148 for the first year and $110,771 each succeeding year.

The bill takes effect on October 1, 2006.

## FULL ANALYSIS

## I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

**Provides limited government**—The bill requires the Division of Health Access and Tobacco to monitor, evaluate and report on the supply and demand of physicians in the state. The bill provides an option to physicians to submit their core credentialing information to specified entities.

B. EFFECT OF PROPOSED CHANGES:

The bill requires the Division of Health Access and Tobacco within the Department of Health to monitor, evaluate and report on the supply and distribution of physicians in the state. The division is required to develop a strategy to track and analyze, on an ongoing basis, the distribution of licensed physicians by specialty and geographic location. The division must use public and private resources for available data. A report must be submitted to the Governor, the President of the Senate, and the Speaker of the House each year starting March 1, 2008.

The bill adds a requirement to the licensure by endorsement and licensure by examination provisions, which require physicians who are seeking licensure to submit their core credentials to either the Federation Credentials Verification Services of the Federation of State Medical Boards or the Department of Health. If they opt to send their credentials to the federation, they must submit a copy of the Physician Information Profile created by the federation to the Department of Health.

The bill provides an appropriation from the General Revenue Fund to the Department of Health to implement the provisions of this bill for Fiscal Year 2006-2007. The bill may be not implemented unless funds are appropriated.

**PRESENT SITUATION**

**Physician Workforce Data**

Recently, the Council on Graduate Medical Education, a national advisory organization that makes recommendations on the adequacy of the supply and distribution of physicians, predicted that the demand for physicians, nationally, would significantly outpace the supply. In Florida, the costs of medical malpractice insurance, the recent adoption of a constitutional amendment that prohibits licensure or continued licensure of physicians who have committed three or more incidents of medical malpractice, and other variables have affected the number of students applying to medical schools in Florida. The number of allopathic and osteopathic physicians applying for licensure and practicing in Florida has also been impacted.

The statewide collection of physician data and its analysis is fragmented in Florida and under the purview of different agencies. Currently, there is no centralized physician workforce database that is available to provide objective statewide information on physician practice and manpower needs.

Under s. 408.05, F.S., the State Center for Health Statistics within the Agency for Health Care Administration (AHCA) must collect data on health resources, including physicians, dentists, nurses, and other health care professionals. The Division of Health Access and Tobacco within DOH administers several programs that relate to physician access. The Florida Medicaid program in AHCA has claims data for physicians participating in the Medicaid program. Although several entities collect information on Florida physicians, there is no centralized responsibility for statewide collection and analysis of health workforce data, including physician data.

**Current Statutory Licensure Requirements**

Chapter 458, F.S., governs the practice of allopathic medicine. Currently, an applicant seeking licensure to practice medicine in Florida must submit specified information regarding education, training and discipline to the Board of Medicine, and must submit an application fee not to exceed $500. The bill amends language into s. 458.311, F.S., that relates to licensure by examination and s. 458.313, F.S., that relates to licensure by endorsement. Both of these sections provide a pathway to licensure.

**Credentialing Process by the Board of Medicine**

As part of the initial licensure process, the staff of the Board of Medicine verifies an applicant's core credentials. The core credentials include medical education, all postgraduate medical training, national licensure examination history, Educational Commission for Foreign Medical Graduates (ECFMG) certification, any current staff privileges, and any physician licenses held in other states, disciplinary history, and medical malpractice claims. Primary source verification of a physician licensure applicant's credentials can be a laborious process, which results in substantial delay in a board's evaluation of an applicant's credentials.

The Florida Board of Medicine encourages, but does not require, licensure applicants to use the Federation Credentials Verification Service (FCVS) to have the applicant's core credentials verified. A one-time fee is assessed by the federation for this service of approximately $275. Additional fees or surcharges may be assessed depending upon what additional information is needed.

**Federation Credentials Verification Service offered by the Federation of State Medical Boards**

Federation Credentials Verification Service (FCVS) was established in September 1996 to provide a centralized, uniform process for state medical boards to obtain a verified, primary source record of a physician's core medical credentials. The FCVS acts as a repository of information for physicians and establishes a confidential, lifetime professional portfolio with FCVS which can be forwarded, at the physician's request, to any state medical board that has established an agreement with FCVS, hospital, health care or any other entity. FCVS obtains primary source verification of medical education, postgraduate training, examination history, board action history, board certification and identity.

This service is designed to lighten the workload of credentialing staff and reduce duplication of effort by gathering, verifying and permanently storing the physician's and/or physician assistant's credentials in a central repository at the federation.

Currently, 38 states *accept* a physician's credentials that are verified by the federation, including Florida. Nine states currently *require* verification by the federation. The bill will make Florida the tenth state to *require* physicians to get verification by the federation.

**Hospital Credentialing and Federation Credentials Verification Service**

Currently, hospitals are not required to recognize the Federation Credentials Verification Service (FCVS). According to information received from the FCVS, limited numbers of hospitals have accepted credentialing from the federation. Since 2001, only 69 medical groups or health care facilities in the state accepted FCVS physician profiles. In comparison, (as of 2005) there were 264 licensed hospitals in the state.

Hospitals and other health care entities are required to meet certain accreditation standards that are set by such entities as the Joint Commission (JCAHO), and the National Committee for Quality Assurance (NCQA) and they are ultimately responsible for the accuracy of employee's credentials. For this reason, a physician could submit their credentials to the FCVS and still be responsible for submitting the identical information to a hospital.

C. SECTION DIRECTORY:

**Section 1.** Creates s. 381.0304, F.S., requiring the Division of Health Access and Tobacco within the Department of Health to monitor, evaluate, and report on the supply and distribution of allopathic and osteopathic physicians in the state, the report shall be submitted annually starting on March 1, 2008.

**Section 2.** Amends s. 458.311, F.S., providing an option for submitting core credentials for licensure by examination.

**Section 3.** Amends s. 458.313, F.S., providing an option for submitting core credentials for licensure by endorsement.

**Sections 4 through 6** amend s. 458.316, 458.3165, and 458.317, F.S., conforming cross-references.

**Section 7.** Provides for an appropriation from the General Revenue Fund and that implementation is contingent upon receiving an appropriation.

**Section 8.** Provides that the bill will take effect on October 1, 2006.

## II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

According to the Department of Health the fiscal impact reflects costs for compiling and evaluating reports of physician licensure data by specialty and location.

1. Revenues:

   No dedicated source of revenue.

2. Expenditures:

| Estimated Expenditures | 1st Year | 2nd Year (Annualized/Recurr.) |
|---|---|---|
| **Salaries** | | |
| 1 FTE Research Associate (no lapse, base + 10% w/28% fringe) - DHAT | $50,340 | $50,340 |
| 1 part time OPS Admin. Support staff at 25 hours/week @$10.00 hour – DHAT | $13,995 | $13,995 |
| 1 part time OPS Operations Management Consultant at 25 hours/week @$17.00 hour -to support desk audit functions - DHAT | $23,791 | $23,791 |
| **Expense** | | |
| DOH Professional Package 1 FTE with limited travel and 1 OPS - DHAT | $23,479 | $16,793 |
| DOH Support Staff Package - DHAT | $7,986 | $5,195 |
| GIS Mapping Software - DHAT | $10,000 | |
| HR Services (1FTE and 2 part-time OPS) – DHAT | $657 | $657 |

| | | |
|---|---|---|
| **OCO** | | |
| Standard OCO professional packages for 1 FTE and 1 OPS - DHAT | $3,800 | 0 |
| Standard OCO package for 1 support staff – DHAT | $2,100 | 0 |
| Other | | |
| Software costs (MQA) | $25,000 | 0 |
| **Total Estimated Expenditures** | $161,148 | $110,771 |

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Physicians may opt to incur the cost of having their core credentials verified by the Federation of State Medical Boards (FSMB). A one-time fee is assessed for this service of approximately $275. Additional fees may be assessed to collect such items as examination transcripts and Educational Commission for Foreign Medical Graduates (ECFMG) Program certification.[1] Physicians, who complete the verification process conducted by the federation, establish a life-long file of their credentials, which can be easily accessed throughout their career by potential employers, state licensure, hospital privileges, and professional memberships. This may also be beneficial for foreign trained physicians who may have difficulty accessing or gathering core credentialing information from the medical school they attended in another country.

D. FISCAL COMMENTS:

According to the Department of Health, the cost to implement the provisions of the bill will be $161,148 for the first year and $110,771 each succeeding year.

## III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not require counties or municipalities to spend funds or take an action requiring the expenditure of funds. This bill does not reduce the percentage of a state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

3. Other:

None.

[1] The Educational Commission for Foreign Medical Graduates (ECFMG) assesses whether international medical graduates met minimum standards of eligibility to include the verification of education. In order for international medical graduates to receive licensure to practice medicine in Florida, applicants must have ECFMG certification.

B. RULE-MAKING AUTHORITY:

No additional rulemaking authority is required to implement the provisions of this bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

According to the Department of Health, current data sources, particularly the department's MQA licensure data, are not sufficient to prepare a report on the geographic distribution of physicians by specialty. To prepare an annual report to meet the needs of the Graduate Medical Education Committee and the Community Hospital Education Council, the collection of data on physicians in the DOH licensing process must be expanded.

## IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

On March 22, 2006, the Health Care Regulation Committee adopted four amendments offered by the bill's sponsor. The Committee Substitute differs from the original bill as filed in that it:

- Removes s. 458.347(7)(b), F.S., which was re-enacted to incorporate the language requiring physicians to submit their core credentials to the Federation Credentials Verification Services. This section was included in the bill as a technicality to ensure that the amendment to s. 458.311(1)(g), F.S., dealing with the credentialing by the federation was applied.
- Specifies that workforce data will be collected on allopathic physicians licensed under chapter 458, F.S., and osteopathic physicians licensed under chapter 459, F.S.
- Moves the workforce data reporting date from January 1 to March 1.
- Removes the requirement that physicians must submit their core credentials to the Federation Credentials Verification Services of the Federation of State Medical Boards and makes it optional. A physician may submit their core credentials to the Federation or the Department of Health. If they opt to submit the information to the federation, they must submit to the department the Physician Information Profile that is created by the federation.

The bill, as amended, was reported favorably as a committee substitute. This analysis is drafted to the committee substitute.

CHAMBER ACTION

The Health Care Regulation Committee recommends the following:

**Council/Committee Substitute**

Remove the entire bill and insert:

A bill to be entitled

An act relating to physicians; creating s. 381.0304, F.S.; requiring the Division of Health Access and Tobacco within the Department of Health to monitor, evaluate, and report on the supply and distribution of allopathic physicians and osteopathic physicians in the state; amending ss. 458.311 and 458.313, F.S.; requiring applicants for physician licensure to submit core credentials to specified entities; amending ss. 458.316, 458.3165, and 458.317, F.S.; conforming cross-references; providing an appropriation; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 381.0304, Florida Statutes, is created to read:

381.0304 Supply and distribution of physicians; reports.--The Division of Health Access and Tobacco of the department shall monitor, evaluate, and report on the supply and

distribution of allopathic physicians licensed under chapter 458 and osteopathic physicians licensed under chapter 459 in this state. The division shall develop a strategy to track and analyze, on an ongoing basis, the distribution of state-licensed physicians by specialty and geographic location using data that are available from public and private sources. The division shall submit a report to the Governor, the President of the Senate, and the Speaker of the House of Representatives by March 1, 2008, and annually thereafter.

Section 2. Subsection (1) of section 458.311, Florida Statutes, is amended to read:

458.311 Licensure by examination; requirements; fees.--

(1) Any person desiring to be licensed as a physician, who does not hold a valid license in any state, shall apply to the department on forms furnished by the department. The department shall license each applicant who the board certifies:

(a) Has completed the application form and remitted a nonrefundable application fee not to exceed $500.

(b) Is at least 21 years of age.

(c) Is of good moral character.

(d) Has not committed any act or offense in this or any other jurisdiction which would constitute the basis for disciplining a physician pursuant to s. 458.331.

(e) For any applicant who has graduated from medical school after October 1, 1992, has completed the equivalent of 2 academic years of preprofessional, postsecondary education, as determined by rule of the board, which shall include, at a

minimum, courses in such fields as anatomy, biology, and chemistry prior to entering medical school.

(f) Meets one of the following medical education and postgraduate training requirements:

1.a. Is a graduate of an allopathic medical school or allopathic college recognized and approved by an accrediting agency recognized by the United States Office of Education or is a graduate of an allopathic medical school or allopathic college within a territorial jurisdiction of the United States recognized by the accrediting agency of the governmental body of that jurisdiction;

b. If the language of instruction of the medical school is other than English, has demonstrated competency in English through presentation of a satisfactory grade on the Test of Spoken English of the Educational Testing Service or a similar test approved by rule of the board; and

c. Has completed an approved residency of at least 1 year.

2.a. Is a graduate of an allopathic foreign medical school registered with the World Health Organization and certified pursuant to s. 458.314 as having met the standards required to accredit medical schools in the United States or reasonably comparable standards;

b. If the language of instruction of the foreign medical school is other than English, has demonstrated competency in English through presentation of the Educational Commission for Foreign Medical Graduates English proficiency certificate or by a satisfactory grade on the Test of Spoken English of the

Educational Testing Service or a similar test approved by rule of the board; and

c. Has completed an approved residency of at least 1 year.

3.a. Is a graduate of an allopathic foreign medical school which has not been certified pursuant to s. 458.314;

b. Has had his or her medical credentials evaluated by the Educational Commission for Foreign Medical Graduates, holds an active, valid certificate issued by that commission, and has passed the examination utilized by that commission; and

c. Has completed an approved residency of at least 1 year; however, after October 1, 1992, the applicant shall have completed an approved residency or fellowship of at least 2 years in one specialty area. However, to be acceptable, the fellowship experience and training must be counted toward regular or subspecialty certification by a board recognized and certified by the American Board of Medical Specialties.

(g) Has either submitted core credentials to the Federation Credentials Verification Services of the Federation of State Medical Boards and submitted the Physician Information Profile originating from the Federation Credentials Verification Service to the department or has submitted core credentials directly to the department.

(h) ~~(g)~~ Has submitted to the department a set of fingerprints on a form and under procedures specified by the department, along with a payment in an amount equal to the costs incurred by the Department of Health for the criminal background check of the applicant.

(i) ~~(h)~~ Has obtained a passing score, as established by rule of the board, on the licensure examination of the United States Medical Licensing Examination (USMLE); or a combination of the United States Medical Licensing Examination (USMLE), the examination of the Federation of State Medical Boards of the United States, Inc. (FLEX), or the examination of the National Board of Medical Examiners up to the year 2000; or for the purpose of examination of any applicant who was licensed on the basis of a state board examination and who is currently licensed in at least one other jurisdiction of the United States or Canada, and who has practiced pursuant to such licensure for a period of at least 10 years, use of the Special Purpose Examination of the Federation of State Medical Boards of the United States (SPEX) upon receipt of a passing score as established by rule of the board. However, for the purpose of examination of any applicant who was licensed on the basis of a state board examination prior to 1974, who is currently licensed in at least three other jurisdictions of the United States or Canada, and who has practiced pursuant to such licensure for a period of at least 20 years, this paragraph does not apply.

Section 3. Paragraph (a) of subsection (1) of section 458.313, Florida Statutes, is amended to read:

458.313 Licensure by endorsement; requirements; fees.--

(1) The department shall issue a license by endorsement to any applicant who, upon applying to the department on forms furnished by the department and remitting a fee set by the board not to exceed $500, the board certifies:

(a) Has met the qualifications for licensure in s. 458.311(1)(b)-(h) ~~s. 458.311(1)(b)-(g)~~ or in s. 458.311(1)(b)-(e) and (h) ~~(g)~~ and (3);

Section 4. Subsection (1) of section 458.316, Florida Statutes, is amended to read:

458.316 Public health certificate.--

(1) Any person desiring to obtain a public health certificate shall submit an application fee not to exceed $300 and shall demonstrate to the board that he or she is a graduate of an accredited medical school and holds a master of public health degree or is board eligible or certified in public health or preventive medicine, or is licensed to practice medicine without restriction in another jurisdiction in the United States and holds a master of public health degree or is board eligible or certified in public health or preventive medicine, and shall meet the requirements in s. 458.311(1)(a)-(f) and (h) ~~s. 458.311(1)(a)-(g)~~ and (5).

Section 5. Section 458.3165, Florida Statutes, is amended to read:

458.3165 Public psychiatry certificate.--The board shall issue a public psychiatry certificate to an individual who remits an application fee not to exceed $300, as set by the board, who is a board-certified psychiatrist, who is licensed to practice medicine without restriction in another state, and who meets the requirements in s. 458.311(1)(a)-(f) and (h) ~~s. 458.311(1)(a)-(g)~~ and (5). A recipient of a public psychiatry certificate may use the certificate to work at any public mental

health facility or program funded in part or entirely by state funds.

(1) Such certificate shall:

(a) Authorize the holder to practice only in a public mental health facility or program funded in part or entirely by state funds.

(b) Be issued and renewable biennially if the secretary of the Department of Health and the chair of the department of psychiatry at one of the public medical schools or the chair of the department of psychiatry at the accredited medical school at the University of Miami recommend in writing that the certificate be issued or renewed.

(c) Automatically expire if the holder's relationship with a public mental health facility or program expires.

(d) Not be issued to a person who has been adjudged unqualified or guilty of any of the prohibited acts in this chapter.

(2) The board may take disciplinary action against a certificateholder for noncompliance with any part of this section or for any reason for which a regular licensee may be subject to discipline.

Section 6. Paragraph (a) of subsection (1) of section 458.317, Florida Statutes, is amended to read:

458.317 Limited licenses.--

(1)(a) Any person desiring to obtain a limited license shall:

1. Submit to the board, with an application and fee not to exceed $300, an affidavit stating that he or she has been

licensed to practice medicine in any jurisdiction in the United States for at least 10 years and intends to practice only pursuant to the restrictions of a limited license granted pursuant to this section. However, a physician who is not fully retired in all jurisdictions may use a limited license only for noncompensated practice. If the person applying for a limited license submits a notarized statement from the employing agency or institution stating that he or she will not receive compensation for any service involving the practice of medicine, the application fee and all licensure fees shall be waived. However, any person who receives a waiver of fees for a limited license shall pay such fees if the person receives compensation for the practice of medicine.

2. Meet the requirements in s. 458.311(1)(b)-(f) and (h) ~~s. 458.311(1)(b)-(g)~~ and (5). If the applicant graduated from medical school prior to 1946, the board or its appropriate committee may accept military medical training or medical experience as a substitute for the approved 1-year residency requirement in s. 458.311(1)(f).

Nothing herein limits in any way any policy by the board, otherwise authorized by law, to grant licenses to physicians duly licensed in other states under conditions less restrictive than the requirements of this section. Notwithstanding the other provisions of this section, the board may refuse to authorize a physician otherwise qualified to practice in the employ of any agency or institution otherwise qualified if the agency or institution has caused or permitted violations of the provisions

of this chapter which it knew or should have known were occurring.

Section 7. The sum of $ is appropriated from the General Revenue Fund to the Department of Health for implementing this act during the 2006-2007 fiscal year. This act shall be implemented contingent on an appropriation in the General Appropriations Act.

Section 8. This act shall take effect October 1, 2006.

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. (for drafter's use only)

Bill No. 1093

COUNCIL/COMMITTEE ACTION

| | |
|---|---|
| ADOPTED | __ (Y/N) |
| ADOPTED AS AMENDED | __ (Y/N) |
| ADOPTED W/O OBJECTION | __ (Y/N) |
| FAILED TO ADOPT | __ (Y/N) |
| WITHDRAWN | __ (Y/N) |
| OTHER | _____ |

Council/Committee hearing bill: Health Care Appropriations

Representative Altman offered the following:

**Amendment**

Remove lines 217 through 221 and insert:

Section 7. The Division of Health Access and Tobacco of the Department of Health shall analyze the supply and distribution of Florida-licensed dentists in Medicaid Service Areas one and two of the Agency for Health Care Administration using data that are available from public and private sources. The division shall determine whether such dentists are retired or working full time. The division shall submit a preliminary report to the Governor, the President of the Senate and the Speaker of the House of Representatives by March 1, 2007, which identifies the supply and distribution of Florida-licensed dentists in Medicaid service areas one and two of the Agency for Health Care Administration, indicates whether Florida-licensed dentists in such areas are retired or working full time, and recommends strategies to improve a broader distribution of dentists in these areas if a shortage or maldistribution is determined to exist. The division shall submit a final report to

the presiding officer of each chamber of the Legislature and the Governor by March 1, 2008.

Section 8. The sum of $161,148, of which $110,771 is recurring, and one full-time equivalent position at 36,245 in salary rate is appropriated to the Department of Health from the Medical Quality Assurance Trust Fund to implement this act for Fiscal Year 2006-2007.

========== T I T L E A M E N D M E N T ==========

Remove line 14 and insert

458.317, F.S.; conforming cross-references; requiring the Division of Health Access and Tobacco within the Department of health to report on the supply and distribution of dentists in specified Agency for Health Care Administration Medicaid services areas;

**HOUSE OF REPRESENTATIVES STAFF ANALYSIS**

**BILL #:** HB 1247 CS Developmental Disabilities
**SPONSOR(S):** Kravitz
**TIED BILLS:** **IDEN./SIM. BILLS:** SB 2226

| REFERENCE | ACTION | ANALYST | STAFF DIRECTOR |
|---|---|---|---|
| 1) Elder & Long-Term Care Committee | 6 Y, 0 N, w/CS | DePalma | Walsh |
| 2) Health Care Appropriations Committee | | Speir WFS | Massengale |
| 3) Health & Families Council | | | |
| 4) | | | |
| 5) | | | |

## SUMMARY ANALYSIS

House Bill 1247 CS amends s. 409.912, F.S., and requires the Agency for Health Care Administration to work with the Agency for Persons with Disabilities to develop and seek federal approval to expand the statutorily-required home and community-based waiver serving children who are diagnosed with Familial Dysautonomia to include adults. The bill also amends the nature of this waiver by deleting a requirement that the agencies seek approval for a "model" waiver.

The bill provides that the act is effective upon becoming law.

This bill does not have a fiscal impact.

## FULL ANALYSIS

## I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

**Provide Limited Government and Empower Families**—The bill creates Medicaid eligibility for a new group of individuals.

B. EFFECT OF PROPOSED CHANGES:

### BACKGROUND

### Familial Dysautonomia Syndrome

Familial Dysautonomia (FD)—or Riley-Day Syndrome—is an example of a group of disorders known as "hereditary sensory and autonomic neuropathies" (HSAN) characterized by widespread sensory dysfunction resulting from incomplete development of sensory and autonomic neurons.[1] First identified in a report by Drs. Conrad Riley and Richard Day in 1949, FD is a debilitating disease that is present from birth, and results in lifelong progressive neuronal degeneration.[2]

Prior to 1960, approximately 50 percent of patients suffering from FD died before reaching the age of five.[3] However, recent advances in supportive treatment approaches have extended the life expectancy of individuals with FD, and the probability of reaching age 20 has now increased to 60 percent,[4] and roughly half of patients diagnosed with FD live to the age of 30.

Transmission

Unlike other HSAN, Familial Dysautonomia has been observed only in individuals of Eastern European Jewish Ancestry (Ashkenazi Jewish extraction), and it is estimated that one in 27 individuals of Eastern European Jewish origin are carriers of the FD gene.[5] The Dysautonomia Foundation, Inc., in New York reports that, based on information available from the FD world-wide registry, as of January 2004 there were more than 340 people worldwide living with FD. One-third of these individuals live in the metropolitan New York City area, one-third reside in Israel, and the remaining third live elsewhere in the United States and worldwide.[6] It has been reported by the Agency for Health Care Administration (AHCA) that 18 persons with FD (10 children and 8 adults) are residents of Florida.

Familial Dysautonomia is an autosomal recessive disorder[7], meaning that a child must inherit a copy of the FD gene from each of their birth parents. All parents of children with Familial Dysautonomia are

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[1] *More About FD*, 2005, the NYU School of Medicine Department of Pediatrics Dysautonomia Treatment & Evaluation Center, available at: http://www.med.nyu.edu/fd/fdcenter.html.
[2] *Familial Dysautonomia*, January 10, 2005, report by GeneTest (funded by the National Institutes of Health), available at: http://www.genetests.org/profiles/fd.
[3] *Familial Dysautonomia (FD)*, accessed March 9, 2006, Jewish Genetic Diseases: A Mazornet Guide, available at: http://www.mazornet.com/genetics/familial_dysautonomia.asp.
[4] *Ibid.*
[5] *FD 101: What is FD?*, accessed March 6, 2006, Familial Dysautonomia Hope Foundation, available at: http://www.fdhope.org/FamilialDysautonomia/AboutFD/FD101.htm.
[6] *FD History and Statistics*, accessed March 6, 2006, the Dysautonomia Foundation, Inc., available at: http://www.familialdysautonomia.org/history.htm.
[7] *About Familial Dysautonomia: Genetics*, accessed March 6, 2006, Familial Dysautonomia Hope Foundation, available at: http://www.fdhope.org/FamilialDysautonomia/AboutFD/genetics.htm.

carriers of the recessive gene that transmits the disease, although a parent or carrier of the gene has no symptoms or warning signs of being a carrier until a child's birth.[8]

Symptoms

Familial Dysautonomia primarily affects the body's autonomic nervous system (responsible for the subconscious regulation of bodily functions and the activities of specific organs) and its sensory nervous system (which controls the body's perceptions of hot/cold and taste, and regulates its protective reactions to pain and other external stimuli).[9]

Although symptoms vary with age, the hallmark clinical feature of Familial Dysautonomia is the absence of overflow tears typically associated with emotional crying.[10] Corneal sensitivity and various other severe eye problems occur frequently in FD patients as a result.

Feeding difficultly is observed in 60 percent of infants with FD in the neonatal period, and poor suck and misdirected swallows often persist and put the patient at risk for aspiration pneumonia (a major cause of lung infections). Other clinical manifestations of the disorder include decreased responsiveness to pain and temperature, extreme fluctuations in blood pressure, red blotching of the skin, and increased sweating. Additionally, individuals suffering from Familial Dysautonomia often have delayed acquisition of speech and walking abilities, unsteady gait, breath-holding episodes and poor growth patterns. By age 13, 90 percent of FD patients experience some spinal curvature.[11]

Familial Dysautonomia patients can be expected to function independently if treatment is begun early and major disabilities are avoided. Affected individuals typically are of normal intelligence.

Dysautonomia Crisis

Roughly 40 percent of individuals with FD will react to stressors or stress events (frequently caused by physical infection or emotional events) with what is termed a "dysautonomia crisis." In addition to vomiting, an individual having a dysautonomia crisis experiences elevated heart rate and blood pressure, irritability and insomnia, severe dysphagia and drooling, and excessive sweating and blotching of the face and trunk.[12]

Treatment

As there is still no cure for Familial Dysautonomia, treatment approaches remain preventative, supportive and largely symptomatic. These include:[13]

- Artificial tears.
- Special feeding techniques.
- Special occupational, physical and speech therapies.
- Special drug management of autonomic manifestations.
- Respite care.
- Orthopedic treatment (for complications from tibial torsion and spinal curvature).
- Compensation for labile blood pressures.

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[8] *More About FD*, the NYU School of Medicine Department of Pediatrics Dysautonomia Treatment & Evaluation, *supra*.
[9] What is Familial Dysautonomia?, accessed March 6, 2006, the Dysautonomia Foundation, Inc., available at: http://www.familialdysautonomia.org/whatisfd.htm.
[10] *More About FD*, the NYU School of Medicine Department of Pediatrics Dysautonomia Treatment & Evaluation, *supra*, noting that, although the absence of overflow tears is the most distinctive feature of Familial Dysautonomia, it is typical for a child not to have tears until reaching 7 months of age.
[11] *Ibid.*
[12] *Ibid.*
[13] *Familial Dysautonomia (FD)*, Jewish Genetic Diseases: A Mazornet Guide, *supra*.

Funding for Familial Dysautonomia Services

The Department of Health, Children's Medical Services (CMS), currently provides services to children diagnosed with FD whose families meet certain income limitations. Under certain federal requirements of the Omnibus Budget Reconciliation Act of 1989 (OBRA 89) specifying that Medicaid programs meet children's medical needs, CMS is able to provide care coordination for a range of needed services and therapies. However, CMS does not have funding to provide families of FD children with respite or behavioral services. Persons with FD are not served by the Agency for Persons with Disabilities (APD).[14]

**Medicaid Home and Community-based Waivers**

In 1981, Congress authorized the waiver of certain federal requirements to enable a state to provide home and community-based services (other than room and board) to individuals who would otherwise require institutional care reimbursed by Medicaid. The waiver programs are called "1915(c) waivers." Under 1915(c) waiver authority, states can provide services not traditionally covered by the Medicaid program, as long as these services are integral to preventing an individual's institutionalization. A 1915(c) waiver may include a waiver of the requirements of the following sections of the Social Security Act:[15]

- 1902(a)(1), relating to statewideness. This allows states to target waivers to particular areas of the state where the need is greatest, or perhaps where certain types of providers are available;
- 1902(a)(10)(B), relating to comparability of services. This allows states to make waiver services available to the Medicaid population at large. States use this authority to target services to particular groups, such as elderly individuals, technology-dependent children, or persons with mental retardation or developmental disabilities; and
- 1902(a)(10)(c)(i)(III), relating to community income and resource rules for the medically needy. This allows states to provide Medicaid to individuals who would otherwise be eligible only in an institutional setting, often due to the income and resources of a spouse or parent. States may also use spousal impoverishment rules to determine financial eligibility or waiver services.

A 1915(c) waiver is initially authorized for three years, and renewals are required every five years thereafter. Within the parameters of broad federal guidelines, 1915(c) waiver authority provides states with flexibility in structuring home and community-based waiver programs designed to meet the specific needs of targeted populations. Federal requirements for states choosing to implement a home and community-based waiver program include:

- Demonstrating that provision of waiver services to a target population is no more costly than the cost of services such individuals would receive in an institutional setting.
- Ensuring that measures will be taken to protect the health and welfare of consumers.
- Assuring financial accountability for funds expended under the waiver authority.
- Providing adequate and reasonable provider standards intended to meet the needs of the target population.
- Ensuring that services are provided in accordance with a plan of care.

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[14] The Agency for Persons with Disabilities was formerly the Development Disabilities Program of the Department of Children and Families. Pursuant to s. 20.197(2), APD is charged with administering waivers established to provide services to persons with developmental disabilities. Familial Dysautonomia is not a "developmental disability" pursuant to s. 393.063(10), F.S."

[15] HCBS Waivers Section 1915(c), accessed March 29, 2006, U.S. Department of Health and Human Services Center for Medicare and Medicaid Services, available at: http://www.cms.hhs.gov/MedicaidStWaivProgDemoPGI/05_HCBSWaivers-Section1915(c).asp#TopOfPage.

**Previous Legislation**

Chapter 2005-115, L.O.F., enacting House Bill 17, directed the Agency for Health Care Administration (AHCA) to work with APD in developing a model home and community-based waiver to serve children diagnosed with FD. The legislation required AHCA to seek federal waiver approval and implement the approved waiver, subject to the availability of funds and any limitations provided in the General Appropriations Act. The act also appropriated $171,840 from the General Revenue Fund and $246,160 from the Medical Care Trust Fund for Fiscal Year 2005-2006.

On March 20, 2006, AHCA submitted an application for a section 1915(c) home and community-based waiver to authorize operation of a Familial Dysautonomia Model Home and Community-Based Services Waiver. By electing to structure the waiver as a "Model" waiver,[16] federal regulations require that no more than 200 individuals are to be served by the waiver at any one time.[17]

The Department of Children and Family Services (DCF) reports that, for purposes of establishing Medicaid eligibility under the waiver, children and single adults are considered a "family of one", and only the income and assets of the child or single adult individually are considered by the department when assessing eligibility.

**PROPOSED CHANGES**

House Bill 1247 CS amends s. 409.912(51), F.S., to add adults as participants in the Familial Dysautonomia home and community-based waiver, and to delete a provision specifying that implementation of the waiver is "subject to the availability of funds and any limitations provided in the General Appropriations Act."

By deleting the reference to a "model" home and community-based waiver in s. 409.912(51), F.S., the CS requires that the waiver be structured as a regular home and community-based waiver pursuant to 42 C.F.R. s. 441.305(a). Therefore, the bill makes the 200-participant limited enrollment provision for "model" waivers[18] inapplicable.

C. SECTION DIRECTORY:

**Section 1**: Amends s. 409.912, F.S., adding adults diagnosed with Familial Dysautonomia to the home and community-based waiver developed by AHCA and APD; deleting a provision indicating that implementation of the waiver is subject to the availability of funds and any other limitation provided in the General Appropriations Act.

**Section 2**: Provides that the CS is effective upon becoming a law.

## II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

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[16] The "Model" waiver submitted by AHCA is different from the model waiver authorized under section 134 of the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA 134), commonly referred to as the "Katie Beckett" waiver. A waiver under this provision in TEFRA allows a state to make the full array of Medicaid services available to a disabled child irrespective of the income and assets of the child's parents. Such children are "deemed" eligible. A Katie Beckett waiver is not a means of providing Medicaid funds or services to adults.

[17] 42 C.F.R. s. 441.305(b).

[18] *Ibid.*

2. Expenditures:

   AHCA advises that no additional funding is necessary to administer this legislation.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

AHCA reports that the bill creates no direct economic impact on the private sector.

D. FISCAL COMMENTS:

None.

## III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   This bill does not require counties or municipalities to spend funds or take an action requiring the expenditure of funds. This bill does not reduce the percentage of a state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

Should this legislation be enacted, it would require AHCA to amend its pending application to reflect "regular" waiver status, rather than "model."

## IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

At its April 4, 2006 meeting the Elder and Long-Term Care Committee adopted an amendment to House Bill 1247, removing the appropriations made to AHCA for the purpose of implementing this act during FY 2006-07. Appropriations staff reports that the funds appropriated from the General Revenue and Medical Care Trust Funds for the purpose of implementing the 2005 legislation are recurring and, therefore, no additional appropriations are necessary.

The Committee favorably reported a Committee Substitute, and this analysis is drafted to the Committee Substitute.

CHAMBER ACTION

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The Elder & Long-Term Care Committee recommends the following:

**Council/Committee Substitute**

Remove the entire bill and insert:

A bill to be entitled

An act relating to developmental disabilities; amending s. 409.912, F.S.; requiring the Agency for Health Care Administration to develop a waiver program to serve children and adults with specified disorders; requiring the agency to seek federal approval and implement the approved waiver in the General Appropriations Act; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Subsection (51) of section 409.912, Florida Statutes, is amended to read:

409.912 Cost-effective purchasing of health care.--The agency shall purchase goods and services for Medicaid recipients in the most cost-effective manner consistent with the delivery of quality medical care. To ensure that medical services are effectively utilized, the agency may, in any case, require a confirmation or second physician's opinion of the correct

diagnosis for purposes of authorizing future services under the Medicaid program. This section does not restrict access to emergency services or poststabilization care services as defined in 42 C.F.R. part 438.114. Such confirmation or second opinion shall be rendered in a manner approved by the agency. The agency shall maximize the use of prepaid per capita and prepaid aggregate fixed-sum basis services when appropriate and other alternative service delivery and reimbursement methodologies, including competitive bidding pursuant to s. 287.057, designed to facilitate the cost-effective purchase of a case-managed continuum of care. The agency shall also require providers to minimize the exposure of recipients to the need for acute inpatient, custodial, and other institutional care and the inappropriate or unnecessary use of high-cost services. The agency shall contract with a vendor to monitor and evaluate the clinical practice patterns of providers in order to identify trends that are outside the normal practice patterns of a provider's professional peers or the national guidelines of a provider's professional association. The vendor must be able to provide information and counseling to a provider whose practice patterns are outside the norms, in consultation with the agency, to improve patient care and reduce inappropriate utilization. The agency may mandate prior authorization, drug therapy management, or disease management participation for certain populations of Medicaid beneficiaries, certain drug classes, or particular drugs to prevent fraud, abuse, overuse, and possible dangerous drug interactions. The Pharmaceutical and Therapeutics Committee shall make recommendations to the agency on drugs for

which prior authorization is required. The agency shall inform the Pharmaceutical and Therapeutics Committee of its decisions regarding drugs subject to prior authorization. The agency is authorized to limit the entities it contracts with or enrolls as Medicaid providers by developing a provider network through provider credentialing. The agency may competitively bid single-source-provider contracts if procurement of goods or services results in demonstrated cost savings to the state without limiting access to care. The agency may limit its network based on the assessment of beneficiary access to care, provider availability, provider quality standards, time and distance standards for access to care, the cultural competence of the provider network, demographic characteristics of Medicaid beneficiaries, practice and provider-to-beneficiary standards, appointment wait times, beneficiary use of services, provider turnover, provider profiling, provider licensure history, previous program integrity investigations and findings, peer review, provider Medicaid policy and billing compliance records, clinical and medical record audits, and other factors. Providers shall not be entitled to enrollment in the Medicaid provider network. The agency shall determine instances in which allowing Medicaid beneficiaries to purchase durable medical equipment and other goods is less expensive to the Medicaid program than long-term rental of the equipment or goods. The agency may establish rules to facilitate purchases in lieu of long-term rentals in order to protect against fraud and abuse in the Medicaid program as defined in s. 409.913. The agency may seek federal waivers necessary to administer these policies.

(51) The agency shall work with the Agency for Persons with Disabilities to develop a ~~model~~ home and community-based waiver to serve children and adults who are diagnosed with familial dysautonomia or Riley-Day syndrome caused by a mutation of the IKBKAP gene on chromosome 9. The agency shall seek federal waiver approval and implement the approved waiver ~~subject to the availability of funds and any limitations provided~~ in the General Appropriations Act. The agency may adopt rules to implement this waiver program.

Section 2. This act shall take effect upon becoming a law.

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. (for drafter's use only)

Bill No. **1247 CS**

COUNCIL/COMMITTEE ACTION

| | |
|---|---|
| ADOPTED | __ (Y/N) |
| ADOPTED AS AMENDED | __ (Y/N) |
| ADOPTED W/O OBJECTION | __ (Y/N) |
| FAILED TO ADOPT | __ (Y/N) |
| WITHDRAWN | __ (Y/N) |
| OTHER | _____ |

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Council/Committee hearing bill: Health Care Appropriations

Representative Kravitz offered the following:

**Amendment**

Remove everything after the enacting clause and insert:

Section 1. Subsection (51) of section 409.912, Florida Statutes, is amended to read:

409.912 Cost-effective purchasing of health care.--The agency shall purchase goods and services for Medicaid recipients in the most cost-effective manner consistent with the delivery of quality medical care. To ensure that medical services are effectively utilized, the agency may, in any case, require a confirmation or second physician's opinion of the correct diagnosis for purposes of authorizing future services under the Medicaid program. This section does not restrict access to emergency services or poststabilization care services as defined in 42 C.F.R. part 438.114. Such confirmation or second opinion shall be rendered in a manner approved by the agency. The agency shall maximize the use of prepaid per capita and prepaid aggregate fixed-sum basis services when appropriate and other alternative service delivery and reimbursement methodologies, including competitive bidding pursuant to s. 287.057, designed

to facilitate the cost-effective purchase of a case-managed continuum of care. The agency shall also require providers to minimize the exposure of recipients to the need for acute inpatient, custodial, and other institutional care and the inappropriate or unnecessary use of high-cost services. The agency shall contract with a vendor to monitor and evaluate the clinical practice patterns of providers in order to identify trends that are outside the normal practice patterns of a provider's professional peers or the national guidelines of a provider's professional association. The vendor must be able to provide information and counseling to a provider whose practice patterns are outside the norms, in consultation with the agency, to improve patient care and reduce inappropriate utilization. The agency may mandate prior authorization, drug therapy management, or disease management participation for certain populations of Medicaid beneficiaries, certain drug classes, or particular drugs to prevent fraud, abuse, overuse, and possible dangerous drug interactions. The Pharmaceutical and Therapeutics Committee shall make recommendations to the agency on drugs for which prior authorization is required. The agency shall inform the Pharmaceutical and Therapeutics Committee of its decisions regarding drugs subject to prior authorization. The agency is authorized to limit the entities it contracts with or enrolls as Medicaid providers by developing a provider network through provider credentialing. The agency may competitively bid single-source-provider contracts if procurement of goods or services results in demonstrated cost savings to the state without limiting access to care. The agency may limit its network based on the assessment of beneficiary access to care, provider availability, provider quality standards, time and distance standards for access to care, the cultural competence of the

provider network, demographic characteristics of Medicaid beneficiaries, practice and provider-to-beneficiary standards, appointment wait times, beneficiary use of services, provider turnover, provider profiling, provider licensure history, previous program integrity investigations and findings, peer review, provider Medicaid policy and billing compliance records, clinical and medical record audits, and other factors. Providers shall not be entitled to enrollment in the Medicaid provider network. The agency shall determine instances in which allowing Medicaid beneficiaries to purchase durable medical equipment and other goods is less expensive to the Medicaid program than long-term rental of the equipment or goods. The agency may establish rules to facilitate purchases in lieu of long-term rentals in order to protect against fraud and abuse in the Medicaid program as defined in s. 409.913. The agency may seek federal waivers necessary to administer these policies.

(51) The agency shall work with the Agency for Persons with Disabilities to develop a ~~model~~ home and community-based waiver to serve children and adults who are diagnosed with familial dysautonomia or Riley-Day syndrome caused by a mutation of the IKBKAP gene on chromosome 9. The agency shall seek federal waiver approval and implement the approved waiver subject to the availability of funds and any limitations provided in the General Appropriations Act. The agency may adopt rules to implement this waiver program.

Section 2. This act shall take effect upon becoming a law.

## HOUSE OF REPRESENTATIVES STAFF ANALYSIS

**BILL #:** HB 1365 CS Florida Healthy Kids Corporation Act
**SPONSOR(S):** Davis, M. and others
**TIED BILLS:** None. **IDEN./SIM. BILLS:** SB 2050

| REFERENCE | ACTION | ANALYST | STAFF DIRECTOR |
|---|---|---|---|
| 1) Future of Florida's Families Committee | 6 Y, 0 N, w/CS | Davis | Collins |
| 2) Health Care Appropriations Committee | | Speir | Massengale |
| 3) Health & Families Council | | | |
| 4) | | | |
| 5) | | | |

## SUMMARY ANALYSIS

House Bill 1365 does the following:

- Allows illegal and legal aliens to participate in the Florida KidCare Program.
- Allows the children of state employees to participate in the Florida KidCare Program.
- Repeals the local match requirement for non-Title XXI children.
- Directs the Agency for Health Care Administration (AHCA) to pursue a federal waiver to increase the financial eligibility threshold for Title XXI premium assistance to up to 300 percent of the federal poverty level (FPL) guidelines.
- Allows health and dental plans participating in the Florida Healthy Kids Program to market the program.
- Allows the Florida Healthy Kids Corporation to release certain information concerning a child's application to parents or legal guardians of the child.

The fiscal impact of this bill is $55.6 million ($28 million General Revenue) in Fiscal Year 2006-2007 and $59.8 million ($30.4 million General Revenue) in Fiscal Year 2007-2008.

The bill shall take effect on July 1, 2006.

## FULL ANALYSIS

## I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

**Provide Limited Government and Promote Personal Responsibility**—The bill expands eligibility for state-subsidized health care coverage.

B. EFFECT OF PROPOSED CHANGES:

**BACKGROUND**

**State Children's Health Insurance Program**

The State Children's Health Insurance Program (SCHIP), enacted as part of the Balanced Budget Act of 1997, created Title XXI of the Social Security Act, which provides insurance to uninsured children in low-income families either through a Medicaid expansion, a separate children's health program, or a combination of both. SCHIP was designed as a federal/state partnership, similar to Medicaid, with the goal of expanding health insurance to children whose families earn too much money to be eligible for Medicaid.

Congress set aside approximately $40 billion over 10 years (1998 through 2007) for states to expand health insurance coverage for millions of children. Under SCHIP, the federal government provides a capped amount of funds to states on a matching basis. For the 2005-2006 fiscal year, the federal allocation is $249,329,871 and the federal matching rate is 71.22 percent.

To be eligible for coverage under Title XXI, a child must meet certain eligibility guidelines. The guidelines require the child to meet the following criteria:

- In a household with an income at or below 200 percent of the FLP guidelines ($40,000 for a family of four in 2006).
- Between the ages of birth through age 18.
- Not the dependant of a state employee eligible for state benefits.
- A U.S. citizen or qualified alien.
- Not an inmate of a public institution or patient in an institution for mental diseases.
- Not eligible for Medicaid.

**The Florida KidCare Program**

The statutory framework for KidCare is delineated in s. 409.810 through 409.821, F.S. KidCare has four components each with its own eligibility standards:

- Medicaid:
  - Birth to age 1, with family incomes up to 200 percent of the FPL guidelines.
  - Ages 1 through 5, with family incomes up to 133 percent of the FPL guidelines.
  - Ages 6 through 18, with family incomes up to 100 percent of the FPL guidelines.
  - Ages 19 through 20, with family incomes up to 24 percent of the FPL guidelines.

- Medikids:
  - Children ages 1 through 4 with family incomes above 133 percent up to 200 percent of the FPL guidelines.

- Healthy Kids:
  - Children age 5, with family incomes above 133 percent up to 200 percent of the FPL guidelines.
  - Children age 6 through 18, with family incomes above 100 percent up to 200 percent of the FPL guidelines.
  - A limited number of children who have family incomes above 200 percent of the FPL guidelines are enrolled in the unsubsidized full-pay option in which the family pays the entire cost of the premium, including administrative costs.

- Children's Medical Services (CMS) Network:
  - Children ages birth through age 18 who have serious health care problems. For Title XXI-funded eligible children with special health care needs, the CMS Network receives a capitation payment from the Agency for Health Care Administration to provide services for them. For children who do not qualify for Title XIX- or Title XXI- funded coverage, services are limited and subject to the availability of funds.

2006 Federal Poverty Level Guidelines

| Persons in Family or Household | 100% | 200% |
|---|---|---|
| 1 | $ 9,800 | 19,600 |
| 2 | 13,200 | 26,400 |
| 3 | 16,600 | 33,200 |
| 4 | 20,000 | 40,000 |
| 5 | 23,400 | 46,800 |

The Agency for Health Care Administration (AHCA) administers Medicaid and Medikids. AHCA is also the lead state agency for the federally funded portion of the KidCare Program. The Florida Healthy Kids Corporation (FHKC), pursuant to a contract with AHCA, administers the Healthy Kids component. FHKC's responsibilities include eligibility determination, collection of premiums, contracting with authorized insurers, and the development of benefit packages. CMS is under the Department of Health and administers the CMS Network. For Title XXI-funded children with special health care needs, the CMS Network receives a capitated payment from the Agency for Health Care Administration of approximately $518.00 per child, per month.

Section 409.814(5), F.S., allows a child whose family income is above 200 percent of the FPL guidelines or a child that is not eligible for premium assistance as delineated in statute[1] to participate in KidCare, except Medicaid, if the family pays the full premium without any premium assistance. These children are known as "full-pays." Only Healthy Kids has enrolled full-pays. The Healthy Kids full-pay premium is $110 per child per month. Current law limits the participation of full-pays to no more than 10 percent of total enrollees in the Florida Healthy Kids program to avoid adverse selection.[2]

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[1]Section 409.814(4), F.S., also excludes from premium assistance under KidCare the following children unless they are eligible for Medicaid:
(a) A child who is eligible for coverage under a state health benefit plan on the basis of a family member's employment with a public agency in the state.
(b) A child who is currently eligible for or covered under a family member's group health benefit plan or under other employer health insurance coverage, excluding coverage provided under the Florida Healthy Kids Corporation as established under s. 624.91, provided that the cost of the child's participation is not greater than 5 percent of the family's income. This provision shall be applied during redetermination for children who were enrolled prior to July 1, 2004. These enrollees shall have 6 months of eligibility following redetermination to allow for a transition to the other health benefit plan.
(c) A child who is seeking premium assistance for the Florida KidCare program through employer-sponsored group coverage, if the child has been covered by the same employer's group coverage during the 6 months prior to the family's submitting an application for determination of eligibility under the program.
(d) A child who is an alien, but who does not meet the definition of qualified alien, in the United States.
(e) A child who is an inmate of a public institution or a patient in an institution for mental diseases.
(f) A child who has had his or her coverage in an employer-sponsored health benefit plan voluntarily canceled in the last 6 months, except those children who were on the waiting list prior to March 12, 2004.
(g) A child who is otherwise eligible for KidCare and who has a preexisting condition that prevents coverage under another insurance plan as described in paragraph (b) which would have disqualified the child for KidCare if the child were able to enroll in the plan shall be eligible for KidCare coverage when enrollment is possible.

[2] Adverse selection occurs when too many children who are likely to incur high medical costs join the same health insurance plan. Adverse selection can cause what insurers refer to as a "death spiral." As more sick children join, the health insurance plan must raise premiums to cover cost. As

Section 624.91(3), F.S., establishes eligibility criteria for state-funded premium assistance in the Healthy Kids program. The following categories are eligible for state-funded premium assistance:

- Residents of Florida who are eligible for the Florida KidCare program pursuant to s. 409.814, F.S.
- Legal aliens, who were enrolled in the Healthy Kids program as of January 31, 2004, and who, because of their alien status, that is, are not "qualified aliens," do not qualify for Title XXI federal funds.
- Individuals who turned 19 as of March 31, 2004, who were receiving Healthy Kids coverage prior to the enactment of the Florida KidCare program. This provision is repealed March 31, 2005.
- Dependents of state employees who were enrolled in the Healthy Kids program as of January 31, 2004. Such dependents remained eligible until January 1, 2005.

**Legislative Commission on Migrant and Seasonal Labor**

Originally established in 1970, the Legislative Commission on Migrant and Seasonal Labor (the commission) is responsible for identifying issues, improving conditions and reducing problems affecting migrant and seasonal workers and their families pursuant to s. 450.201, F.S. The commission was somewhat inactive until 2004, when the Legislature renamed the commission and required it to produce a report to the Legislature by February 1 of each year, beginning in 2006.

The commission began meeting in October 2005, to create a forum for discussions of issues of concern to migrant and seasonal laborers and their dependents. The commission heard from various stakeholders with an interest in migrant and seasonal labor issues, including advocacy groups, agriculture industry representatives, state agency personnel, and the farm workers themselves.

Health care for the children of migrant and seasonal laborers surfaced as a topic of major concern. The commission recommended the funding of KidCare benefits for all children of migrant and seasonal laborers. This bill attempts to implement that recommendation by making alien children eligible to participate in KidCare.

**Federal State Children's Health Insurance Program (SCHIP) Waivers**

Federal law sets Title XXI income eligibility at 200 percent of the FPL guidelines. As SCHIP evolved and grew, a new option became available to the states to expand coverage under the program. Since 2000, the federal government allows states to apply for waivers of the income eligibility threshold so they can increase eligibility over 200 percent of the FPL guidelines. The specific authority is a research and demonstration project waiver, authorized by Section 1115 of the Social Security Act, also known as a "Section 1115 waiver." This authority allows the secretary of Health and Human Services to waive certain provisions in the legislation of some "grant-in-aid" programs such as Medicaid—and now SCHIP—to authorize a pilot or demonstration project aimed at promoting the objectives of the program. It also allows the secretary to provide matching funds where such funds normally are not available.

The Centers for Medicare and Medicaid Services (CMS), released the Section 1115 waiver guidance for SCHIP to states on July 31, 2000. The guidance describes factors to be considered in granting states permission to implement state-devised approaches that ordinarily are not permitted under the SCHIP law in order to meet programmatic goals and objectives and still receive an enhanced match rate. CMS examines the overall state approach instead of basing its decision solely on the criteria

provided in the guidance. These demonstration projects can be used to research an issue of interest to CMS, to test a program, or to otherwise fulfill a research purpose. Section 1115 demonstration projects are given five years in which to prove their research and public policy value. The demonstration projects must contain specific objectives and an evaluation component.

Most importantly from a fiscal perspective, all state activities under SCHIP 1115 waivers must be "budget neutral." In the case of SCHIP, this means "allotment neutrality," that is, a state cannot exceed its individual SCHIP funds allotment. Reallocated funds from previously unspent SCHIP allotments do not count toward the available amount. Rules on budget neutrality and funding differ somewhat between SCHIP Medicaid expansions and SCHIP state-designed programs. In the case of Medicaid expansion 1115 waivers, a state could receive funds from a Medicaid amendment or waiver should its SCHIP allotment run out. If an SCHIP demonstration waiver is operated under an SCHIP state-designed program, no more federal funds are available once SCHIP funds are exhausted. Three possible options are generally possible for an SCHIP demonstration waiver. It can expand benefits and services; expand coverage to new populations; or both.

Expanded services and benefits can be provided to discrete populations as long as these services do not substitute for existing services funded by state or federal money. The two types of additional services are: supplemental services and public health initiatives.

New populations—such as parents of eligible children, pregnant women and children age 18 to 21 otherwise eligible for SCHIP—could be covered under a SCHIP 1115 demonstration waiver. Adults with no children and who are not pregnant will not be considered an eligible population for demonstration projects. Other demonstration waivers that CMS has said it would consider are the following:

- Extending coverage for children who become ineligible for SCHIP because of their age while in treatment for a specific condition.
- Proposals to promote enrollment of children eligible for other programs such as the free and reduced school lunch program and the Healthy Start program.

**Effect**

The bill amends s. 409.811, F.S., adding a definition of "Healthy Kids" as a component of the Florida KidCare program of medical assistance for children 5 through 18 years of age as authorized under s. 624.91, F.S., and administered by the Florida Healthy Kids Corporation. The bill adds a definition of the "maximum income threshold" as a percentage of the current FPL guidelines used to determine eligibility for certain program components, as approved by federal waiver or an amendment to the state plan.

The bill amends s. 409.8132, F.S., changing the set income eligibility from 200 percent of the FPL guidelines to the maximum income threshold and changing a reference to the Health Care Financing Administration to the Centers for Medicare and Medicaid Services.

Year-round open enrollment is conditioned on the Social Service Estimating Conference determining that state and federal funds are sufficient to fund the increased enrollment through federal fiscal year 2007 when SCHIP is scheduled to sunset under federal law. This bill amends s. 409.8134, F.S., removing references to federal and state funding and removing a reference to funding through 2007.

The bill amends s. 409.814, F.S., to change the income eligibility ceiling from 200 percent of the FPL to the maximum income threshold. Section 409.814, F.S., is also amended to allow alien children, both illegal and legal, and children of state employees to participate in KidCare.

The bill requires AHCA to seek approval from CMS for a waiver to increase the income eligibility ceiling to 300 percent of the FPL guidelines. Until the waiver is approved, the maximum income threshold used for the Florida KidCare program shall be 200 percent of the FPL or the highest income threshold allowed under current federal law. Any such expansion under this subsection is subject to a specified appropriation.

The bill amends s. 409.821, F.S., clarifying that FHKC may release certain information concerning a child's application to parents or legal guardians of the child.

The bill amends s. 624.91, F.S., revising eligibility for nonfederal premium assistance in the Florida Healthy Kids program.

The largest category affected under the bill would be legal aliens who do not qualify for Title XXI federal funds because of their alien status, according to AHCA representatives. By removing the current qualification that these children had to have been enrolled in Healthy Kids prior to January 31, 2004, the bill would allow children who have moved to Florida since February 1, 2004, or have become uninsured, the opportunity to receive Healthy Kids coverage. Also, children from families with incomes within 200 percent of the FPL guidelines, but who do not meet all of the other technical eligibility factors, would be able to apply for subsidized state coverage.

FHKC is currently required to establish a local match policy for the enrollment of non-Title XXI children in the Florida Healthy Kids program. At minimum the local match must equal what is required in the General Appropriations Act. The bill repeals the requirement for local match for non-Title XXI children.

The bill allows participating health and dental plans to develop marketing and other promotional materials and participate in activities, such as health fairs and public events, as approved by FHKC.

C. SECTION DIRECTORY:

**Section 1.** Amends s. 409.811, F.S., adding a definition of "Healthy Kids"; and a definition of the "maximum income threshold."

**Section 2.** Amends s. 409.8132, F.S., changing the set income eligibility from 200 percent of the FPL guidelines to the maximum income threshold; inserting a cross reference; and changing a reference to the Health Care Financing Administration to the Centers for Medicare and Medicaid Services.

**Section 3.** Amends s. 409.8134, F.S., removing references to federal and state funding and removing a reference to funding through 2007.

**Section 4.** Amends s. 409.814, F.S., changing the set income eligibility from 200 percent of the FPL guidelines to the maximum income threshold; specifying groups that are not eligible for federal premium assistance; and specifying children that are eligible for nonfederal premium assistance.

**Section 5.** Amends s. 409.816, F.S., correcting a cross reference.

**Section 6.** Amends s. 409.818, F.S., requiring AHCA to seek a federal waiver to increase the income eligibility ceiling.

**Section 7.** Amends s. 409.821, F.S., clarifying that FHKC may release certain information concerning a child's application to parents or legal guardians of the child.

**Section 8.** Amends s. 624.91, F.S., revising eligibility for nonfederal premium assistance in the Florida Healthy Kids program; repealing the requirement for local match for nonfederal premium assistance; allowing participating health and dental plans to market and promote.

**Section 9.** The bill takes effect July 1, 2006.

## II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

| **Recurring Expenditures** | 2006-2007 | 2007-2008 |
|---|---|---|
| General Revenue Fund | $28,084,800 | $30,422,980 |
| Grants and Donations Trust Fund | $ 4,517,440 | $ 4,517,440 |
| Medical Care Trust Fund | $22,957,864 | $24,884,658 |
| Total Funds | $55,560,104 | $59,825,078 |

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   See Fiscal Comments section.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Non-Title XXI children not currently in the Florida Healthy Kids program would benefit under the provisions of this bill because such children could receive benefits under the program.

Health and dental plan providers would receive economic benefit from increased enrollment in their plans.

D. FISCAL COMMENTS:

The expenditures estimate above presumes that the caseload for non-Title XXI children will increase by 13,703 children and that the Legislature will provide an appropriation for these children. Since these children do not receive federal match, the state will have to appropriate general revenue to pay for their health benefits. It is estimated that the cost of the health and dental benefits and administrative costs for these children will be $18.8 million in Fiscal Year 2006-2007 and $20.3 million in Fiscal Year 2007-2008.

The expenditure estimate above presumes the federal waiver will be approved. Currently, there are 25,347 full-pay children whose family income is below 300 percent of the FPL guidelines participating in the Florida Healthy Kids program. It is presumed that all these children will be covered by the waiver and the cost of their benefits will be picked up by the state and federal government. The cost to the state is presumed to be $9.3 million for Fiscal Year 2006-2007 and $10 million for Fiscal Year 2007-2008. This estimate is probably low because there are more children with family incomes between 200 percent and 300 percent of the FPL guidelines than just those currently participating as full-pays.

Local governments currently contribute to the premium cost to purchase benefits for non-Title XXI children. The proviso in the General Appropriations Act for the current year requires a local match of $7 million. This bill removes the requirement that local governments contribute to the premium cost to purchase benefits for non-Title XXI children.

## III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   The bill does not require counties or municipalities to spend funds or to take an action requiring the expenditure of funds. The bill does not reduce the percentage of a state tax shared with counties or municipalities. The bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

The bill does not provide rulemaking authority to FHKC.

C. DRAFTING ISSUES OR OTHER COMMENTS:

## IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

On April 5, 2006, the Future of Florida's Families committee adopted a Committee Substitute to House Bill 1365. The substantive changes made in the committee substitute include changing provisions related to the maximum income threshold in the Florida KidCare program and revising provisions relating to the Healthy Kid Corporation. The bill analysis reflects these changes.

CHAMBER ACTION

The Future of Florida's Families Committee recommends the following:

**Council/Committee Substitute**

Remove the entire bill and insert:

A bill to be entitled

An act relating to the Florida KidCare program; amending s. 409.811, F.S.; defining the terms "Healthy Kids" and "maximum income threshold"; amending s. 409.8132, F.S.; providing that eligibility for the Florida KidCare program be at or below the maximum income threshold rather than a specified percentage of the federal poverty level; conforming and updating references; amending s. 409.8134, F.S.; conforming provisions to changes made by the act; amending s. 409.814, F.S.; requiring that eligibility for the Florida KidCare program be at or below the maximum income threshold rather than a specified percentage of the federal poverty level; providing that certain specified children are eligible for nonfederal premium assistance for health insurance; providing that a child whose family income is above the maximum income threshold may participate in the Florida KidCare program but is subject to certain conditions; amending s. 409.816, F.S.;

conforming a cross-reference; amending s. 409.818, F.S.; requiring the Agency for Health Care Administration to seek approval from the federal Centers for Medicare and Medicaid Services to use the highest maximum income threshold allowed by federal law or regulation, which is up to 300 percent of the most recently stated federal poverty limit; providing an alternative eligibility standard pending approval of the request; amending s. 409.821, F.S., relating to a public-records exemption; specifying that such provision does not prohibit an enrollee's parent or legal guardian from obtaining confirmation of coverage and dates of coverage; amending s. 624.91, F.S.; conforming provisions to changes made by the act; revising the powers of the Florida Healthy Kids Corporation; authorizing participating health and dental plans to develop marketing and other promotional materials and to participate in activities to promote the Florida Healthy Kids Corporation; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 409.811, Florida Statutes, is amended to read:

409.811 Definitions relating to Florida KidCare Act.--As used in ss. 409.810-409.820, the term:

(1) "Actuarially equivalent" means that:

(a) The aggregate value of the benefits included in health benefits coverage is equal to the value of the benefits in the benchmark benefit plan; and

(b) The benefits included in health benefits coverage are substantially similar to the benefits included in the benchmark benefit plan, except that preventive health services must be the same as in the benchmark benefit plan.

(2) "Agency" means the Agency for Health Care Administration.

(3) "Applicant" means a parent or guardian of a child or a child whose disability of nonage has been removed under chapter 743, who applies for determination of eligibility for health benefits coverage under ss. 409.810-409.820.

(4) "Benchmark benefit plan" means the form and level of health benefits coverage established in s. 409.815.

(5) "Child" means any person under 19 years of age.

(6) "Child with special health care needs" means a child whose serious or chronic physical or developmental condition requires extensive preventive and maintenance care beyond that required by typically healthy children. Health care utilization by such a child exceeds the statistically expected usage of the normal child adjusted for chronological age, and such a child often needs complex care requiring multiple providers, rehabilitation services, and specialized equipment in a number of different settings.

(7) "Children's Medical Services Network" or "network" means a statewide managed care service system as defined in s. 391.021(1).

(8) "Community rate" means a method used to develop premiums for a health insurance plan that spreads financial risk across a large population and allows adjustments only for age, gender, family composition, and geographic area.

(9) "Department" means the Department of Health.

(10) "Enrollee" means a child who has been determined eligible for and is receiving coverage under ss. 409.810-409.820.

(11) "Enrollment ceiling" means the maximum number of children receiving premium assistance payments, excluding children enrolled in Medicaid, that may be enrolled at any time in the Florida KidCare program. The maximum number shall be established annually in the General Appropriations Act or by general law.

(12) "Family" means the group or the individuals whose income is considered in determining eligibility for the Florida KidCare program. The family includes a child with a custodial parent or caretaker relative who resides in the same house or living unit or, in the case of a child whose disability of nonage has been removed under chapter 743, the child. The family may also include other individuals whose income and resources are considered in whole or in part in determining eligibility of the child.

(13) "Family income" means cash received at periodic intervals from any source, such as wages, benefits, contributions, or rental property. Income also may include any money that would have been counted as income under the Aid to

Families with Dependent Children (AFDC) state plan in effect prior to August 22, 1996.

(14) "Florida KidCare program," "KidCare program," or "program" means the health benefits program administered through ss. 409.810-409.820.

(15) "Guarantee issue" means that health benefits coverage must be offered to an individual regardless of the individual's health status, preexisting condition, or claims history.

(16) "Health benefits coverage" means protection that provides payment of benefits for covered health care services or that otherwise provides, either directly or through arrangements with other persons, covered health care services on a prepaid per capita basis or on a prepaid aggregate fixed-sum basis.

(17) "Health insurance plan" means health benefits coverage under the following:

(a) A health plan offered by any certified health maintenance organization or authorized health insurer, except a plan that is limited to the following: a limited benefit, specified disease, or specified accident; hospital indemnity; accident only; limited benefit convalescent care; Medicare supplement; credit disability; dental; vision; long-term care; disability income; coverage issued as a supplement to another health plan; workers' compensation liability or other insurance; or motor vehicle medical payment only; or

(b) An employee welfare benefit plan that includes health benefits established under the Employee Retirement Income Security Act of 1974, as amended.

(18) "Healthy Kids" means a component of the Florida KidCare program of medical assistance for children 5 through 18 years of age as authorized under s. 624.91 and administered by the Florida Healthy Kids Corporation.

(19) "Maximum income threshold" means a percentage of the current federal poverty level used to determine eligibility for certain program components, as approved by federal waiver or an amendment to the state plan.

(20) ~~(18)~~ "Medicaid" means the medical assistance program authorized by Title XIX of the Social Security Act, and regulations thereunder, and ss. 409.901-409.920, as administered in this state by the agency.

(21) ~~(19)~~ "Medically necessary" means the use of any medical treatment, service, equipment, or supply necessary to palliate the effects of a terminal condition, or to prevent, diagnose, correct, cure, alleviate, or preclude deterioration of a condition that threatens life, causes pain or suffering, or results in illness or infirmity and which is:

(a) Consistent with the symptom, diagnosis, and treatment of the enrollee's condition;

(b) Provided in accordance with generally accepted standards of medical practice;

(c) Not primarily intended for the convenience of the enrollee, the enrollee's family, or the health care provider;

(d) The most appropriate level of supply or service for the diagnosis and treatment of the enrollee's condition; and

(e) Approved by the appropriate medical body or health care specialty involved as effective, appropriate, and essential for the care and treatment of the enrollee's condition.

(22) ~~(20)~~ "Medikids" means a component of the Florida KidCare program of medical assistance authorized by ~~Title XXI of the Social Security Act, and regulations thereunder, and~~ s. 409.8132, as administered in the state by the agency.

(23) ~~(21)~~ "Preexisting condition exclusion" means, with respect to coverage, a limitation or exclusion of benefits relating to a condition based on the fact that the condition was present before the date of enrollment for such coverage, whether or not any medical advice, diagnosis, care, or treatment was recommended or received before such date.

(24) ~~(22)~~ "Premium" means the entire cost of a health insurance plan, including the administration fee or the risk assumption charge.

(25) ~~(23)~~ "Premium assistance payment" means the monthly consideration paid by the agency per enrollee in the Florida KidCare program towards health insurance premiums.

(26) ~~(24)~~ "Qualified alien" means an alien as defined in s. 431 of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, as amended, Pub. L. No. 104-193.

(27) ~~(25)~~ "Resident" means a United States citizen, or qualified alien, who is domiciled in this state.

(28) ~~(26)~~ "Rural county" means a county having a population density of less than 100 persons per square mile, or a county defined by the most recent United States Census as rural, in

which there is no prepaid health plan participating in the Medicaid program as of July 1, 1998.

(29) ~~(27)~~ "Substantially similar" means that, with respect to additional services as defined in s. 2103(c)(2) of Title XXI of the Social Security Act, these services must have an actuarial value equal to at least 75 percent of the actuarial value of the coverage for that service in the benchmark benefit plan and, with respect to the basic services as defined in s. 2103(c)(1) of Title XXI of the Social Security Act, these services must be the same as the services in the benchmark benefit plan.

Section 2. Subsections (6) and (7) of section 409.8132, Florida Statutes, are amended to read:

409.8132 Medikids program component.--

(6) ELIGIBILITY.--

(a) A child who has attained the age of 1 year but who is under the age of 5 years is eligible to enroll in the Medikids program component of the Florida KidCare program, if the child is a member of a family that has a family income which exceeds the Medicaid applicable income level as specified in s. 409.903, but which is equal to or below the maximum income threshold ~~200 percent of the current federal poverty level~~. In determining the eligibility of ~~such~~ a child, an assets test is not required. A child who is eligible for Medikids may elect to enroll in Florida Healthy Kids coverage or employer-sponsored group coverage. However, a child who is eligible for Medikids may participate in the Florida Healthy Kids program only if the child has a sibling participating in the Florida Healthy Kids

program and the child's county of residence permits such enrollment.

(b) The provisions of s. 409.814(3), (4), ~~and~~ (5), and (6) are ~~shall be~~ applicable to the Medikids program.

(7) ENROLLMENT.--Enrollment in the Medikids program component may occur at any time throughout the year. A child may not receive services under the Medikids program until the child is enrolled in a managed care plan or MediPass. Once determined eligible, an applicant may receive choice counseling and select a managed care plan or MediPass. The agency may initiate mandatory assignment for a Medikids applicant who has not chosen a managed care plan or MediPass provider after the applicant's voluntary choice period ends. An applicant may select MediPass under the Medikids program component only in counties that have fewer than two managed care plans available to serve Medicaid recipients and only if the federal Centers for Medicare and Medicaid Services ~~Health Care Financing Administration~~ determines that MediPass constitutes "health insurance coverage" as defined in Title XXI of the Social Security Act.

Section 3. Subsection (2) of section 409.8134, Florida Statutes, is amended to read:

409.8134 Program enrollment and expenditure ceilings.--

(2) The Florida KidCare program may conduct enrollment at any time throughout the year for the purpose of enrolling children eligible for all program components listed in s. 409.813 except Medicaid. The four Florida KidCare administrators shall work together to ensure that the year-round enrollment period is announced statewide. Eligible children shall be

enrolled on a first-come, first-served basis using the date the enrollment application is received. Enrollment shall immediately cease when the enrollment ceiling is reached. Year-round enrollment shall only be held if the Social Services Estimating Conference determines that sufficient ~~federal and state~~ funds will be available to finance the increased enrollment ~~through federal fiscal year 2007~~. Any individual who is not enrolled must reapply by submitting a new application. The application for the Florida KidCare program is ~~shall be~~ valid for a period of 120 days after the date it was received. At the end of the 120-day period, if the applicant has not been enrolled in the program, the application is ~~shall be~~ invalid and the applicant shall be notified of the action. The applicant may resubmit the application after notification of the action taken by the program. Except for the Medicaid program, whenever the Social Services Estimating Conference determines that there are presently, or will be by the end of the current fiscal year, insufficient funds to finance the current or projected enrollment in the Florida KidCare program, all additional enrollment must cease and additional enrollment may not resume until sufficient funds are available to finance the ~~such~~ enrollment.

Section 4. Section 409.814, Florida Statutes, is amended to read:

409.814 Eligibility.--A child who has not reached 19 years of age whose family income is equal to or below the maximum income threshold ~~200 percent of the federal poverty level~~ is eligible for the Florida KidCare program as provided in this

section. For enrollment in the Children's Medical Services Network, a complete application includes the medical or behavioral health screening. If, subsequently, an individual is determined to be ineligible for coverage, he or she must immediately be disenrolled from the respective Florida KidCare program component.

(1) A child who is eligible for Medicaid coverage under s. 409.903 or s. 409.904 must be enrolled in Medicaid and is not eligible to receive health benefits under any other health benefits coverage authorized under the Florida KidCare program.

(2) A child who is not eligible for Medicaid, but who is eligible for the Florida KidCare program, may obtain health benefits coverage under any of the other components listed in s. 409.813 if such coverage is approved and available in the county in which the child resides. However, a child who is eligible for Medikids may participate in the Florida Healthy Kids program only if the child has a sibling participating in the Florida Healthy Kids program and the child's county of residence permits such enrollment.

(3) A child who is eligible for the Florida KidCare program who is a child with special health care needs, as determined through a medical or behavioral screening instrument, is eligible for health benefits coverage from and shall be referred to the Children's Medical Services Network.

(4) The following children are not eligible to receive federal premium assistance for health benefits coverage under the Florida KidCare program, except under Medicaid if the child

would have been eligible for Medicaid under s. 409.903 or s. 409.904 as of June 1, 1997:

(a) A child who is eligible for coverage under a state health benefit plan on the basis of a family member's employment with a public agency in the state.

(b) A child who is currently eligible for or covered under a family member's group health benefit plan or under other employer health insurance coverage, excluding coverage provided under the Florida Healthy Kids Corporation as established under s. 624.91, provided that the cost of the child's participation is not greater than 5 percent of the family's income. This provision shall be applied during redetermination for children who were enrolled prior to July 1, 2004. These enrollees shall have 6 months of eligibility following redetermination to allow for a transition to the other health benefit plan.

(c) A child who is seeking premium assistance for the Florida KidCare program through employer-sponsored group coverage, if the child has been covered by the same employer's group coverage during the 6 months prior to the family's submitting an application for determination of eligibility under the program.

(d) A child who is an alien, but who does not meet the definition of qualified alien, in the United States.

(e) A child who is an inmate of a public institution or a patient in an institution for mental diseases.

(f) A child who has had his or her coverage in an employer-sponsored health benefit plan voluntarily canceled in

the last 6 months, except those children who were on the waiting list prior to March 12, 2004.

(g) A child who is otherwise eligible for KidCare and who has a preexisting condition that prevents coverage under another insurance plan as described in paragraph (b) which would have disqualified the child for KidCare if the child were able to enroll in the plan shall be eligible for KidCare coverage when enrollment is possible.

(5) Subject to a specific appropriation for this purpose, the following children are eligible to receive nonfederal premium assistance for health benefits coverage under the Florida KidCare program, except under Medicaid if the child would have been eligible for Medicaid under s. 409.903 or s. 409.904 as of June 1, 1997:

(a) A child who is eligible for coverage under a state health benefit plan on the basis of a family member's employment with a public agency in the state.

(b) A child who is an alien in the United States but who does not meet the definition of qualified alien.

(6) ~~(5)~~ A child whose family income is above the maximum income threshold ~~200 percent of the federal poverty level~~ or a child who is excluded under the provisions of subsection (4) may participate in the Florida KidCare program, excluding the Medicaid program, but is subject to the following provisions:

(a) The family is not eligible for premium assistance payments and must pay the full cost of the premium, including any administrative costs.

(b) The agency is authorized to place limits on enrollment in Medikids by these children in order to avoid adverse selection. The number of children participating in Medikids whose family income exceeds the maximum income threshold ~~200 percent of the federal poverty level~~ must not exceed 10 percent of total enrollees in the Medikids program.

(c) The board of directors of the Florida Healthy Kids Corporation is authorized to place limits on enrollment of these children in order to avoid adverse selection. In addition, the board is authorized to offer a reduced benefit package to these children in order to limit program costs for such families. The number of children participating in the Florida Healthy Kids program whose family income exceeds the maximum income threshold ~~200 percent of the federal poverty level~~ must not exceed 10 percent of total enrollees in the Florida Healthy Kids program.

(d) Children described in this subsection are not counted in the annual enrollment ceiling for the Florida KidCare program.

(7) ~~(6)~~ Once a child is enrolled in the Florida KidCare program, the child is eligible for coverage under the program for 12 months without a redetermination or reverification of eligibility, if the family continues to pay the applicable premium. Eligibility for program components funded through Title XXI of the Social Security Act shall terminate when a child attains the age of 19. Effective January 1, 1999, a child who has not attained the age of 5 and who has been determined eligible for the Medicaid program is eligible for coverage for

12 months without a redetermination or reverification of eligibility.

(8) ~~(7)~~ When determining or reviewing a child's eligibility under the Florida KidCare program, the applicant shall be provided with reasonable notice of changes in eligibility which may affect enrollment in one or more of the program components. When a transition from one program component to another is authorized, there shall be cooperation between the program components and the affected family which promotes continuity of health care coverage. Any authorized transfers must be managed within the program's overall appropriated or authorized levels of funding. Each component of the program shall establish a reserve to ensure that transfers between components will be accomplished within current year appropriations. These reserves shall be reviewed by each convening of the Social Services Estimating Conference to determine the adequacy of such reserves to meet actual experience.

(9) ~~(8)~~ In determining the eligibility of a child, an assets test is not required. Each applicant shall provide written documentation during the application process and the redetermination process, including, but not limited to, the following:

(a) Proof of family income, which must include a copy of the applicant's most recent federal income tax return. In the absence of a federal income tax return, an applicant may submit wages and earnings statements (pay stubs), W-2 forms, or other appropriate documents.

(b) A statement from all family members that:

1. Their employer does not sponsor a health benefit plan for employees; or

2. The potential enrollee is not covered by the employer-sponsored health benefit plan because the potential enrollee is not eligible for coverage, or, if the potential enrollee is eligible but not covered, a statement of the cost to enroll the potential enrollee in the employer-sponsored health benefit plan.

(10) ~~(9)~~ Subject to paragraph (4)(b) and s. 624.91(3), the Florida KidCare program shall withhold benefits from an enrollee if the program obtains evidence that the enrollee is no longer eligible, submitted incorrect or fraudulent information in order to establish eligibility, or failed to provide verification of eligibility. The applicant or enrollee shall be notified that because of such evidence program benefits will be withheld unless the applicant or enrollee contacts a designated representative of the program by a specified date, which must be within 10 days after the date of notice, to discuss and resolve the matter. The program shall make every effort to resolve the matter within a timeframe that will not cause benefits to be withheld from an eligible enrollee.

(11) ~~(10)~~ The following individuals may be subject to prosecution in accordance with s. 414.39:

(a) An applicant obtaining or attempting to obtain benefits for a potential enrollee under the Florida KidCare program when the applicant knows or should have known the potential enrollee does not qualify for the Florida KidCare program.

(b) An individual who assists an applicant in obtaining or attempting to obtain benefits for a potential enrollee under the Florida KidCare program when the individual knows or should have known the potential enrollee does not qualify for the Florida KidCare program.

Section 5. Subsection (3) of section 409.816, Florida Statutes, is amended to read:

409.816 Limitations on premiums and cost-sharing.--The following limitations on premiums and cost-sharing are established for the program.

(3) Enrollees in families with a family income above 150 percent of the federal poverty level, who are not receiving coverage under the Medicaid program or who are not eligible under s. 409.814(6) ~~s. 409.814(5)~~, may be required to pay enrollment fees, premiums, copayments, deductibles, coinsurance, or similar charges on a sliding scale related to income, except that the total annual aggregate cost-sharing with respect to all children in a family may not exceed 5 percent of the family's income. However, copayments, deductibles, coinsurance, or similar charges may not be imposed for preventive services, including well-baby and well-child care, age-appropriate immunizations, and routine hearing and vision screenings.

Section 6. Subsection (3) of section 409.818, Florida Statutes, is amended to read:

409.818 Administration.--In order to implement ss. 409.810-409.820, the following agencies shall have the following duties:

(3) The Agency for Health Care Administration, under the authority granted in s. 409.914(1), shall:

(a) Calculate the premium assistance payment necessary to comply with the premium and cost-sharing limitations specified in s. 409.816. The premium assistance payment for each enrollee in a health insurance plan participating in the Florida Healthy Kids Corporation shall equal the premium approved by the Florida Healthy Kids Corporation and the Office of Insurance Regulation of the Financial Services Commission pursuant to ss. 627.410 and 641.31, less any enrollee's share of the premium established within the limitations specified in s. 409.816. The premium assistance payment for each enrollee in an employer-sponsored health insurance plan approved under ss. 409.810-409.820 shall equal the premium for the plan adjusted for any benchmark benefit plan actuarial equivalent benefit rider approved by the Office of Insurance Regulation pursuant to ss. 627.410 and 641.31, less any enrollee's share of the premium established within the limitations specified in s. 409.816. In calculating the premium assistance payment levels for children with family coverage, the agency shall set the premium assistance payment levels for each child proportionately to the total cost of family coverage.

(b) Annually calculate the program enrollment ceiling based on estimated per child premium assistance payments and the estimated appropriation available for the program.

(c) Make premium assistance payments to health insurance plans on a periodic basis. The agency may use its Medicaid fiscal agent or a contracted third-party administrator in making

these payments. The agency may require health insurance plans that participate in the Medikids program or employer-sponsored group health insurance to collect premium payments from an enrollee's family. Participating health insurance plans shall report premium payments collected on behalf of enrollees in the program to the agency in accordance with a schedule established by the agency.

(d) Monitor compliance with quality assurance and access standards developed under s. 409.820.

(e) Establish a mechanism for investigating and resolving complaints and grievances from program applicants, enrollees, and health benefits coverage providers, and maintain a record of complaints and confirmed problems. In the case of a child who is enrolled in a health maintenance organization, the agency must use the provisions of s. 641.511 to address grievance reporting and resolution requirements.

(f) Approve health benefits coverage for participation in the program, following certification by the Office of Insurance Regulation under subsection (4).

(g) Adopt rules necessary for calculating premium assistance payment levels, calculating the program enrollment ceiling, making premium assistance payments, monitoring access and quality assurance standards, investigating and resolving complaints and grievances, administering the Medikids program, and approving health benefits coverage.

The agency is designated the lead state agency for Title XXI of the Social Security Act for purposes of receipt of federal

funds, for reporting purposes, and for ensuring compliance with federal and state regulations and rules. The agency shall seek approval from the federal Centers for Medicare and Medicaid Services for the highest maximum income threshold of up to 300 percent of the most recently stated federal poverty limit. Until the federal agency approves the request, the maximum income threshold used for the Florida KidCare program shall be 200 percent of the most recently stated federal poverty limit or the highest income threshold allowed under current federal law. Any such expansion under this subsection is subject to a specified appropriation for such purpose.

Section 7. Section 409.821, Florida Statutes, is amended to read:

409.821 Florida KidCare program public records exemption.--Notwithstanding any other law to the contrary, any information identifying a Florida KidCare program applicant or enrollee, as defined in s. 409.811, held by the Agency for Health Care Administration, the Department of Children and Family Services, the Department of Health, or the Florida Healthy Kids Corporation is confidential and exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution. Such information may be disclosed to another governmental entity only if disclosure is necessary for the entity to perform its duties and responsibilities under the Florida KidCare program and shall be disclosed to the Department of Revenue for purposes of administering the state Title IV-D program. The receiving governmental entity must maintain the confidential and exempt status of such information. Furthermore, such information may

not be released to any person without the written consent of the program applicant. This exemption applies to any information identifying a Florida KidCare program applicant or enrollee held by the Agency for Health Care Administration, the Department of Children and Family Services, the Department of Health, or the Florida Healthy Kids Corporation before, on, or after the effective date of this exemption. A violation of this section is a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083. This section does not prohibit an enrollee's parent or legal guardian from obtaining confirmation of coverage and dates of coverage.

Section 8. Subsections (3) and (5) of section 624.91, Florida Statutes, are amended to read:

624.91 The Florida Healthy Kids Corporation Act.--

(3) ELIGIBILITY FOR NONFEDERAL ~~STATE-FUNDED~~ ASSISTANCE.--Only residents of this state between 5 and 18 years of age who meet the qualifications for the Florida KidCare program under s. 409.814 are eligible for nonfederal assistance in the Florida Healthy Kids program. ~~the following individuals are eligible for state-funded assistance in paying Florida Healthy Kids premiums:~~

~~(a) Residents of this state who are eligible for the Florida KidCare program pursuant to s. 409.814.~~

~~(b) Notwithstanding s. 409.814, legal aliens who are enrolled in the Florida Healthy Kids program as of January 31, 2004, who do not qualify for Title XXI federal funds because they are not qualified aliens as defined in s. 409.811.~~

~~(c) Notwithstanding s. 409.814, individuals who have attained the age of 19 as of March 31, 2004, who were receiving Florida Healthy Kids benefits prior to the enactment of the Florida KidCare program. This paragraph shall be repealed March 31, 2005.~~

~~(d) Notwithstanding s. 409.814, state employee dependents who were enrolled in the Florida Healthy Kids program as of January 31, 2004. Such individuals shall remain eligible until January 1, 2005.~~

(5) CORPORATION AUTHORIZATION, DUTIES, PROMOTION, POWERS.--

(a) There is created the Florida Healthy Kids Corporation, a not-for-profit corporation.

(b) The Florida Healthy Kids Corporation shall:

1. Arrange for the collection of any family, local contributions, or employer payment or premium, in an amount to be determined by the board of directors, to provide for payment of premiums for comprehensive insurance coverage and for the actual or estimated administrative expenses.

~~2. Arrange for the collection of any voluntary contributions to provide for payment of premiums for children who are not eligible for medical assistance under Title XXI of the Social Security Act. Each fiscal year, the corporation shall establish a local match policy for the enrollment of non-Title-XXI-eligible children in the Healthy Kids program. By May 1 of each year, the corporation shall provide written notification of the amount to be remitted to the corporation for the following fiscal year under that policy. Local match sources may include,~~

~~but are not limited to, funds provided by municipalities, counties, school boards, hospitals, health care providers, charitable organizations, special taxing districts, and private organizations. The minimum local match cash contributions required each fiscal year and local match credits shall be determined by the General Appropriations Act. The corporation shall calculate a county's local match rate based upon that county's percentage of the state's total non-Title XXI expenditures as reported in the corporation's most recently audited financial statement. In awarding the local match credits, the corporation may consider factors including, but not limited to, population density, per capita income, and existing child health related expenditures and services.~~

2.~~3.~~ Subject to the provisions of s. 409.8134, accept voluntary supplemental local match contributions that comply with the requirements of Title XXI of the Social Security Act for the purpose of providing additional coverage in contributing counties under Title XXI.

3.~~4.~~ Establish the administrative and accounting procedures for the operation of the corporation.

4.~~5.~~ Establish, with consultation from appropriate professional organizations, standards for preventive health services and providers and comprehensive insurance benefits appropriate to children, provided that the ~~such~~ standards for rural areas do ~~shall~~ not limit primary care providers to board-certified pediatricians.

5.~~6.~~ Determine eligibility for children seeking to participate in the ~~Title XXI funded components of the~~ Florida

KidCare program consistent with the requirements specified in s. 409.814~~, as well as the non-Title-XXI-eligible children as provided in subsection (3)~~.

6.~~7.~~ Establish procedures under which ~~providers of local match to,~~ applicants to and participants in the program may have grievances reviewed by an impartial body and reported to the board of directors of the corporation.

7.~~8.~~ Establish participation criteria and, if appropriate, contract with an authorized insurer, health maintenance organization, or third-party administrator to provide administrative services to the corporation.

8.~~9.~~ Establish enrollment criteria that ~~which shall~~ include penalties or waiting periods of not fewer than 60 days for reinstatement of coverage upon voluntary cancellation for nonpayment of family premiums.

9.~~10.~~ Contract with authorized insurers or any provider of health care services, meeting standards established by the corporation, for the provision of comprehensive insurance coverage to participants. Such standards shall include criteria under which the corporation may contract with more than one provider of health care services in program sites. Health plans shall be selected through a competitive bid process. The Florida Healthy Kids Corporation shall purchase goods and services in the most cost-effective manner consistent with the delivery of quality medical care. The maximum administrative cost for a Florida Healthy Kids Corporation contract shall be 15 percent. For health care contracts, the minimum medical loss ratio for a Florida Healthy Kids Corporation contract shall be 85 percent.

For dental contracts, the remaining compensation to be paid to the authorized insurer or provider under a Florida Healthy Kids Corporation contract shall be no less than an amount which is 85 percent of premium; to the extent any contract provision does not provide for this minimum compensation, this section shall prevail. The health plan selection criteria and scoring system, and the scoring results, shall be available upon request for inspection after the bids have been awarded.

~~11. Establish disenrollment criteria in the event local matching funds are insufficient to cover enrollments.~~

10.~~12.~~ Develop and implement a plan to publicize the Florida Healthy Kids Corporation, the eligibility requirements of the program, and the procedures for enrollment in the program and to maintain public awareness of the corporation and the program. Participating health and dental plans may develop marketing and other promotional materials and participate in activities, such as health fairs and public events, as approved by the corporation. The health and dental plans may also contact their enrollees and former enrollees to encourage continued participation in the plan.

11.~~13.~~ Secure staff necessary to properly administer the corporation. Staff costs shall be funded from state and local matching funds and such other private or public funds as become available. The board of directors shall determine the number of staff members necessary to administer the corporation.

12.~~14.~~ Provide a report annually to the Governor, Chief Financial Officer, Commissioner of Education, Senate President,

Speaker of the House of Representatives, and Minority Leaders of the Senate and the House of Representatives.

13.~~15.~~ Establish benefit packages which conform to the provisions of the Florida KidCare program, as created in ss. 409.810-409.820.

(c) Coverage under the corporation's program is secondary to any other available private coverage held by, or applicable to, the participant child or family member. Insurers under contract with the corporation are the payors of last resort and must coordinate benefits with any other third-party payor that may be liable for the participant's medical care.

(d) The Florida Healthy Kids Corporation shall be a private corporation not for profit, organized under ~~pursuant to~~ chapter 617, and shall have all powers necessary to carry out the purposes of this act, including, but not limited to, the power to receive and accept grants, loans, or advances of funds from any public or private agency and to receive and accept from any source contributions of money, property, labor, or any other thing of value, to be held, used, and applied for the purposes of this section ~~act~~.

Section 9. This act shall take effect July 1, 2006.

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. (for drafter's use only)

Bill No. 1365 CS

COUNCIL/COMMITTEE ACTION

| | |
|---|---|
| ADOPTED | __ (Y/N) |
| ADOPTED AS AMENDED | __ (Y/N) |
| ADOPTED W/O OBJECTION | __ (Y/N) |
| FAILED TO ADOPT | __ (Y/N) |
| WITHDRAWN | __ (Y/N) |
| OTHER | _____ |

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Council/Committee hearing bill: Health Care Appropriations

Representative M. Davis offered the following:

**Amendment**

Remove the entire bill and insert:

A bill to be entitled

An act relating to the Florida KidCare program; amending s. 409.814 clarifying 12-months of continuous eligibility includes changes between components; amending s. 409.821, F.S., relating to a public-records exemption; specifying that such provision does not prohibit an enrollee's parent or legal guardian from obtaining confirmation of coverage and dates of coverage; creating s. 409.8125, F.S., authorizing participating health and dental plans to develop marketing and other promotional materials and to participate in activities to promote the Florida KidCare Program; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Subsection (6) of section 409.814, Florida Statutes, is amended to read:

409.814 Eligibility.--A child who has not reached 19 years of age whose family income is equal to or below 200 percent of the federal poverty level is eligible for the Florida KidCare program as provided in this section. For enrollment in the Children's Medical Services Network, a complete application includes the medical or behavioral health screening. If, subsequently, an individual is determined to be ineligible for coverage, he or she must immediately be disenrolled from the respective Florida KidCare program component.

(6) Once a child is enrolled in the Florida KidCare program, the child is eligible for coverage under the program for 12 months without a redetermination or reverification of eligibility <u>even when switching from one component of the program to another</u>, if the family continues to pay the applicable premium. Eligibility for program components funded through Title XXI of the Social Security Act shall terminate when a child attains the age of 19. Effective January 1, 1999, a child who has not attained the age of 5 and who has been determined eligible for the Medicaid program is eligible for coverage for 12 months without a redetermination or reverification of eligibility.

Section 2. Section 409.821, Florida Statutes, is amended to read:

409.821 Florida KidCare program public records exemption.--Notwithstanding any other law to the contrary, any information identifying a Florida KidCare program applicant or enrollee, as defined in s. 409.811, held by the Agency for Health Care Administration, the Department of Children and Family Services, the Department of Health, or the Florida Healthy Kids Corporation is confidential and exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution. Such information may be

disclosed to another governmental entity only if disclosure is necessary for the entity to perform its duties and responsibilities under the Florida KidCare program and shall be disclosed to the Department of Revenue for purposes of administering the state Title IV-D program. The receiving governmental entity must maintain the confidential and exempt status of such information. Furthermore, such information may not be released to any person without the written consent of the program applicant. This exemption applies to any information identifying a Florida KidCare program applicant or enrollee held by the Agency for Health Care Administration, the Department of Children and Family Services, the Department of Health, or the Florida Healthy Kids Corporation before, on, or after the effective date of this exemption. A violation of this section is a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083. This section does not prohibit an enrollee's parent or legal guardian from obtaining confirmation of coverage and dates of coverage.

Section 3. Section 409.8215, Florida Statutes, is created to read:

409.8215 – Marketing by Service Providers.

(1) Participating health and dental plans may develop marketing and other promotional materials and participate in activities, such as health fairs and public events, as approved by the Agency for Health Care Administration.

(2) The health and dental plans may also contact their enrollees and former enrollees to encourage continued participation in the KidCare Program.

(3) The agency may adopt rules pursuant to ss. 120.536 and 120.54 to implement the provisions of this section.

Section 4. This act shall take effect July 1, 2006.

Amendment No. (for drafter's use only)

## HOUSE OF REPRESENTATIVES STAFF ANALYSIS

**BILL #:** HB 1417 CS Hospices
**SPONSOR(S):** Sansom
**TIED BILLS:** **IDEN./SIM. BILLS:** CS/SB 1598

| REFERENCE | ACTION | ANALYST | STAFF DIRECTOR |
|---|---|---|---|
| 1) Elder & Long-Term Care Committee | 8 Y, 0 N, w/CS | DePalma | Walsh |
| 2) Health Care Appropriations Committee | | Speir WFS | Massengale SM |
| 3) Health & Families Council | | | |
| 4) | | | |
| 5) | | | |

### SUMMARY ANALYSIS

House Bill 1417 CS amends the definition of "hospice" contained in s. 400.601(3), F.S., to remove the requirement that hospices be organized as not-for-profit corporations, and directs the Office of Program Policy Analysis and Government Accountability to submit a report by January 1, 2010 analyzing the impact of for-profit hospices on the delivery of care to terminally ill patients in the state. Additionally, the bill provides legislative intent that no change in law or in administrative rule be made to licensure and certificate of need provisions until 2012.

The bill requires all entities in the state offering, describing or advertising hospice services to state the year of initial state licensure, and specifies that state hospices must serve the entire hospice area for which it is licensed.

The bill directs the Agency for Health Care Administration to deny a license or renewal of a license to any hospice that fails to meet any commitment in the certificate of need application, and requires hospices to use trained volunteers in an amount equal to at least 5 percent of total patient care hours of all paid employees and staff.

The bill also requires the Department of Elderly Affairs, in conjunction with the Agency for Health Care Administration and all hospices licensed in Florida, to develop quality and effectiveness outcome measures, consider and adopt national initiatives, and develop an annual report.

The bill appears to have no fiscal impact on state or local government.

The bill provides a severability clause, and an effective date of July 1, 2006.

## FULL ANALYSIS

## I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

**Safeguard Individual Liberty**—The bill allows for-profit hospices to be licensed in Florida, subject to certificate of need requirements.

B. EFFECT OF PROPOSED CHANGES:

**BACKGROUND**

**Hospice Care for Terminally ill Patients**

Hospice care is an alternative approach to the traditional medical model for end-of-life care. Hospice programs specialize in providing basic medical care, palliation and pain management, and social, psychological, and spiritual support to terminally-ill[1] individuals and their families. In Fiscal Year 2004-2005, Florida hospice programs provided care to more than 98,000 individuals with terminal illnesses.[2] Nationally, the number of individuals receiving hospice care has increased 300 percent in the last decade, from 340,000 hospice patients in 1994 to 1,060,000 patients in 2004.[3]

With one exception, s. 400.601(3), F.S., requires hospice programs to operate as not-for-profit corporations, as defined in chapter 617, F.S.[4] Section 400.602(5), F.S., authorizes a hospice that was incorporated on or before July 1, 1978 to be transferred to a for-profit or not-for-profit entity, while s. 400.602(6), F.S., further permits any entity entitled to licensure under s. 400.602(5), F.S., to obtain a license for up to two additional hospices.[5]

Two for-profit entities, Vitas Healthcare Corporation of Florida and Vitas Healthcare Corporation of Central Florida, each purchased a not-for-profit hospice established before July 1, 1978 in accordance with s. 400.602(5), F.S. Both Vitas Healthcare Corporation of Florida and Vitas Healthcare Corporation of Central Florida have obtained licenses for two additional hospices,[6] as permitted in s. 400.602(6), F.S. There are only four remaining hospices that were incorporated on or before July 1, 1978, that could be sold to for-profit hospices pursuant to s. 400.602(5), F.S.:

- Hospice of the Florida Suncoast (Pinellas County).
- Hospice of St. Francis (Brevard County).
- Hospice of Palm Beach County.
- Hospice of Gold Coast Home Health Services (Broward County).

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[1] To be eligible for hospice services in Florida, patients must receive a referral from their attending or primary physician for hospice care based on a diagnosis of a terminal illness with a life expectancy of one year or less, per s. 400.601(10), F.S.

[2] *Florida's Certificate of Need Process Ensures Qualified Hospice Programs; Performance Reporting Is Important to Assess Hospice Quality,* Report 06-29, March 2006, Office of Program Policy Analysis and Government Accountability.

[3] *NHPCO's 2004 Facts and Figures*, accessed March 23, 2006, National Hospice and Palliative Care Organization, available at: http://www.nhpco.org/files/public/Facts_Figures_for2004data.pdf.

[4] A not-for-profit corporation is defined in s. 617.01401(5), F.S., as a corporation, no part of the income or profit of which is distributable to its members, directors, or officers.

[5] Such entity may obtain a license for up to two additional hospices "in accordance with the other requirements of this part and upon receipt of any certificate of need that may be required under the provisions of ss. 408.031-408.045, F.S."

[6] On March 23, 2006, the license status of the hospice run by Vitas Healthcare Corporations of Florida in Boynton Beach, Florida (Palm Beach County) indicated that the facility had received a provisional license pending necessary background screening. Hospice licenses can be reviewed at http://facilitylocator.floridahealthstat.com/FacilityFind.aspx?pFaclType=22&pFaclName=&pFaclCity=&pFaclZip=&pCounty=ALL&pFaclInspectionRegion=ALL.

All entities desiring a license to provide hospice services in the state must first obtain a certificate of need (CON) from the Agency for Health Care Administration (AHCA). Under s. 408.043(2), F.S., the need for a new or expanded hospice must be determined on the basis of the need for, and availability of, hospice services in the community. Other guidelines provide the following:

- The formula on which the CON is based must discourage regional monopolies and promote competition.
- The inpatient hospice care component of a hospice which is a freestanding facility, or a part of a facility, which is primarily engaged in providing inpatient care and related services and is not licensed as a health care facility, must also be required to obtain a CON.
- Provision of hospice care by any current provider of health care is a significant change in service, and therefore requires a CON for such services.

AHCA has established 27 service areas for hospices[7] as follows:

- Service Area 1 consists of Escambia, Okaloosa, Santa Rosa, and Walton Counties.
- Service Area 2A consists of Bay, Calhoun, Gulf, Holmes, Jackson, and Washington Counties.
- Service Area 2B consists of Franklin, Gadsden, Jefferson, Leon, Liberty, Madison, Taylor, and Wakulla Counties.
- Service Area 3A consists of Alachua, Bradford, Columbia, Dixie, Gilchrist, Hamilton, Lafayette, Levy, Putnam, Suwannee, and Union Counties.
- Service Area 3B consists of Marion County.
- Service Area 3C consists of Citrus County.
- Service Area 3D consists of Hernando County.
- Service Area 3E consists of Lake and Sumter Counties.
- Service Area 4A consists of Baker, Clay, Duval, Nassau, and St. Johns Counties.
- Service Area 4B consists of Flagler and Volusia Counties.
- Service Area 5A consists of Pasco County.
- Service Area 5B consists of Pinellas County.
- Service Area 6A consists of Hillsborough County.
- Service Area 6B consists of Hardee, Highlands, and Polk Counties.
- Service Area 6C consists of Manatee County.
- Service Area 7A consists of Brevard County.
- Service Area 7B consists of Orange and Osceola Counties.
- Service Area 7C consists of Seminole County.
- Service Area 8A consists of Charlotte and DeSoto Counties.
- Service Area 8B consists of Collier County.
- Service Area 8C consists of Glades, Hendry and Lee Counties.
- Service Area 8D consists of Sarasota County.
- Service Area 9A consists of Indian River County.
- Service Area 9B consists of Martin, Okeechobee, and St. Lucie Counties.
- Service Area 9C consists of Palm Beach County.
- Service Area 10 consists of Broward County.
- Service Area 11 consists of Dade and Monroe Counties.

**OPPAGA Review of Florida's Hospice Care Industry**

Pursuant to a legislative request, the Office of Program Policy Analysis and Government Accountability (OPPAGA) performed a review of the state's hospice industry in March 2006, as well as a survey of the

[7] Rule 59C-1.0355, F.A.C.

various approaches to regulating hospice facilities utilized by eight other states,[8] in an effort to evaluate Florida's system of providing hospice care to terminally-ill patients.[9] According to the report,

> Florida's method of regulating hospice programs differs from other states in two major ways. Florida is the only state that requires new hospice programs to operate as not-for-profit corporations and is one of only 12 states that comprehensively regulates the growth of hospice programs using a Certificate of Need process.[10]

OPPAGA reports ownership status does not appear to affect performance of hospice programs

Noting that available information on the issue is limited, OPPAGA reported that "ownership status does not appear to affect hospice care in Florida or in other states." Hospice officials in states authorizing both not-for-profit and for-profit hospice facilities reported having no evidence suggesting that ownership status affects the quality of hospice care provided.

Additionally, OPPAGA noted that there was no significant difference in the number of complaints or allegations received by AHCA relating to either not-for-profit or for-profit hospice programs, though the total number of hospice allegations in the state was small.[11]

OPPAGA recommended that the Legislature direct AHCA and the Department of Elderly Affairs (DOEA) to work with Florida hospice programs to develop standardized quality and outcome measures, as well as a mechanism for collecting and maintaining such information. Moreover, the report urged hospice programs in the state to consider participating in national initiatives such as those developed by the National Hospice and Palliative Care Organization (NHPCO).

OPPAGA recommends continued CON approval for new hospice programs

OPPAGA further recommended that, if it elected to license new for-profit hospice programs in the state, the Legislature should maintain its current CON process. The OPPAGA report indicated that such process "ensures that new hospice programs operate only in areas of the state where current hospice programs are not able to meet projected hospice needs," thereby preventing an excess of hospice facilities within a single geographic locale. OPPAGA reported that the CON process also ensures that "hospice programs have the expertise, financial resources, and commitment to meet the needs of their communities."

OPPAGA noted that AHCA is currently exploring modifications to its methodology for identifying areas of the state where existing programs may not be meeting the need for hospice care services.

## EFFECT OF PROPOSED CHANGES

House Bill 1417 CS amends the definition of "hospice" contained in s. 400.601(3), F.S., to remove the requirement that hospices be organized as a not-for-profit corporation, as defined in chapter 617, F.S., and directs OPPAGA to submit a report by January 1, 2010 to the President and of the Senate and the Speaker of the House of Representatives analyzing the impact of for-profit hospices on the delivery of care to terminally ill patients in the state. Such report is required to include a review of the quality of care offered by for-profit hospices, changes in the competitive marketplace in hospice service areas, and any other information deemed pertinent.

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[8] The eight states surveyed (Alabama, Illinois, Maryland, Virginia, Ohio, Tennessee, Texas, and California) are similar to Florida in terms of either size and/or elderly population.

[9] *Florida's Certificate of Need Process Ensures Qualified Hospice Programs; Performance Reporting Is Important to Assess Hospice Quality*, Office of Program Policy Analysis and Government Accountability, *supra.*

[10] Ibid.

[11] Between August, 2002 and July, 2005, AHCA received a total of only 279 allegations pertaining to hospice operations.

Consequently, the bill also deletes ss. 400.602(5) and (6), F.S., relating to the ability of hospices incorporated prior to July 1, 1978 to be transferred to a for-profit entity, and thereafter obtain licensure for up to two additional hospices.

The bill requires all entities in the state offering, describing, or advertising hospice services to state the year of initial licensure as a hospice in the state or the year of initial licensure of the hospice entity or affiliate based in the state that owns the hospice, both directly beneath the name of the licensed entity in a font no less than 25 percent of the font size for the entity's name or other indication of hospice services, and prominently at least one time on any document, item, or other medium offering, describing, or advertising hospice services or hospice-like services.

State hospices are required by the bill to serve the entire hospice service area for which they are licensed, and, for counties in the service area with a population of 50,000 or less,[12] a hospice must have a plan for providing care, meeting the needs for hospice care, and for reporting access and utilization for county residents, and must locate an office in the county and employ local hospice staff or trained volunteers within six months after initial licensure.

The bill requires AHCA to deny a license or renewal of a license to any hospice that fails to meet any commitment for the provision of hospice care or services made in the application for certificate of need or any condition for the provision of hospice care or services specified in the certificate of need, unless such hospice is able to demonstrate that meeting a commitment or condition is premature to the initial issuance of a license.

Hospices are required by the bill to use trained volunteers in defined roles and under the supervision of a designated hospice employee, in an amount that equals at least 5 percent of total patient care hours provided by all paid hospice employees and contract staff in the aggregate. The bill also requires a hospice to document and report the use of volunteers, including a record of the number of volunteers and the number of hours and the tasks performed by each volunteer.

The bill provides legislative intent that no change in law or in administrative rule be made to the hospice licensure and certificate of need provisions until 2012, in order to correctly analyze and evaluate the impact of this act on the quality of hospice care in the state.

By December 31, 2007, the Department of Elderly Affairs (DOEA), in consultation with AHCA and all hospices licensed in the state, is required to develop outcome measures to determine the quality and effectiveness of hospice care in Florida. At a minimum, the bill requires these outcome measures to include a requirement that 50 percent of patients reporting severe pain on a 0 to 10 scale report a reduction to 5 or less by the end of the fourth day of care.

The bill also requires DOEA, in conjunction with AHCA and all hospices licensed in the state, to consider and adopt national initiatives, such as those developed by the National Hospice and Palliative Care Organization, to set benchmarks for measuring the quality of hospice care provided in the state; and to develop an annual report that analyzes and evaluates information collected under various data collection or reporting provisions.

The bill provides a severability clause, and an effective date of July 1, 2006.

C. SECTION DIRECTORY:

**Section 1.** Amends s. 400.601(3), F.S., deleting the requirement that a hospice be a not-for-profit corporation, organized pursuant to Chapter 617, F.S.

[12] Pursuant to s. 1.01(7), F.S., reference to the population of any county of the state shall be taken to be that as shown by the last preceding official decennial federal census.

**Section 2.** Amends s. 400.602, F.S., specifying certain advertising and distribution requirements; requiring that a hospice serve the entire service area for which it is licensed, and that a hospice have a plan for providing hospice care in counties in a service area with a population of 50,000 or less; deleting provisions relating to the ability of hospices incorporated prior to July 1, 1978 to be transferred to a for-profit entity.

**Section 3.** Amends s. 400.606, F.S., requiring AHCA to deny a license or renewal where a hospice fails to meet any commitment for the provision of hospice care or services made in the application for certificate of need.

**Section 4.** Amends s. 400.6105, F.S., requiring a hospice to use trained volunteers, and establishing documentation and reporting requirements.

**Section 5.** Directing OPPAGA to submit a report analyzing the impact of for-profit hospices on the delivery of care to terminally-ill patients by January 1, 2010.

**Section 6.** Providing legislative intent that no change in law or in administrative rule be made to the hospice licensure and certificate of need provisions until the year 2012.

**Section 7.** Requiring DOEA, in conjunction with AHCA and all hospices licensed in Florida, to develop certain outcome measures by December 31, 2007, as well as consider and adopt certain national initiatives, and develop an annual report.

**Section 8.** Providing severability.

**Section 9.** Providing an effective date of July 1, 2006.

## II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   Both the Department of Elderly Affairs and AHCA report that, although department staff will need to evaluate data and generate certain reports, such tasks can be completed within current department and agency resources.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

While the fiscal impact of allowing for-profit hospice facilities in the state is presently unknown, the bill directs OPPAGA to submit a report analyzing the impact of for-profit hospices on the delivery and quality of hospice care, as well as reviewing changes in the competitive marketplace in hospice service areas, by January 1, 2010.

D. FISCAL COMMENTS:

None.

## III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Counties and municipalities are unaffected by this legislation.

2. Other:

See "Drafting Issues" below.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The legislative intent provided in Section 6 of the bill that "no change in law or in administrative rule be made to the hospice licensure and certificate of need provisions until 2012 ..." leaves unanswered the question of what time in the year 2012 the Legislature intends to permit or pursue legislative or administrative rule changes. Further, to the extent the intent seeks to bind the action of future legislatures, it is likely that the language will be viewed as aspirational in effect.[13]

## IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

At its March 28, 2006 meeting, the Committee on Elder and Long-Term Care adopted a strike-all amendment to House Bill 1417:

- Amends the definition of "hospice" in s. 400.601, F.S., to remove the requirement that a hospice be organized as a not-for-profit corporation under chapter 617, F.S..
- Provides that an entity offering hospice services must state the year of initial state licensure directly beneath the name of the licensed entity in a font no less than 25 percent of the font size for the entity's name, and prominently at least one time on any document, item, or other medium offering, describing, or advertising hospice services.
- Requires that a hospice serve the entire service area for which it is licensed and, for counties in the service area with a population of 50,000 or less, requiring a hospice to have a plan for providing hospice care and meeting the needs for hospice care and for reporting access and utilization for the county residents, and to locate an office in the county with local hospice staff or trained volunteers within six months of initial licensure.

[13] See *Neu v. Miami Herald Pub. Co.*, 462 So. 2d 821 (Fla. 1985).

- Deletes sections (5) and (6) of s. 400.602, F.S., relating to the ability of hospices incorporated prior to July 1, 1978 to be transferred to a for-profit entity, and thereafter obtain licensure for up to two additional hospices.
- Requires AHCA to deny a license or renewal of a license to any hospice that fails to meet any commitment for the provision of hospice care or services made in the application for certificate of need or any condition for the provision of hospice care or services specified in the certificate of need, unless such hospice can demonstrate that meeting a commitment or condition is premature to the initial issuance of a license.
- Requires hospices to use trained volunteers in an amount that equals 5 percent of total patient care hours of all paid hospice employees and contract staff, and providing certain documentation and reporting requirements.
- Directs OPPAGA to submit a report by January 1, 2010 to the President of the Senate and the Speaker of the House of Representatives that analyzes the impact of for-profit hospices on the delivery and quality of care to terminally-ill patients and reviews changes in the competitive marketplace in hospice service areas.
- Provides legislative intent that no change in law or in administrative rule be made to the hospice licensure and certificate of need provisions until the year 2012.
- Requires DOEA, in conjunction with AHCA and all hospices licensed in the state, to develop certain outcome measures to determine the quality and effectiveness of hospice care in Florida by December 31, 2007, to consider and adopt national initiatives setting benchmarks for measuring the quality of hospice care provided in the state, and to develop an annual report that analyzes and evaluates information collected under various data collection or reporting provisions.
- Provides a severability clause.

The Committee favorably reported a Committee Substitute for the bill, and this analysis is drafted to that Committee Substitute.

CHAMBER ACTION

The Elder & Long-Term Care Committee recommends the following:

**Council/Committee Substitute**

Remove the entire bill and insert:

A bill to be entitled

An act relating to hospices; amending s. 400.601, F.S.; revising the definition of the term "hospice"; amending s. 400.602, F.S.; requiring that a hospice state the year of initial licensure in the state; prescribing the manner and placement of such notification; requiring a hospice to serve a specified area, provide certain services, and employ staff and trained volunteers within a specified time period; deleting provisions authorizing the transfer of certain hospices and the acquisition of additional licenses; amending s. 400.606, F.S.; requiring the Agency for Health Care Administration to deny a license or renewal of a license to hospices that fail to meet certain conditions; amending s. 400.6105, F.S.; requiring a hospice to use trained volunteers and to document and report certain volunteer information; requiring the Office of Program Policy Analysis and Government Accountability to submit a report to the Legislature; providing legislative intent; providing that the Department of

Elderly Affairs, in conjunction with the agency and all hospices licensed in the state, develop certain outcome measures; providing for adoption of national initiatives; requiring an annual report; providing for severability; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Subsection (3) of section 400.601, Florida Statutes, is amended to read:

400.601 Definitions.--As used in this part, the term:

(3) "Hospice" means a centrally administered corporation ~~not-for-profit, as defined in chapter 617,~~ providing a continuum of palliative and supportive care for the terminally ill patient and his or her family.

Section 2. Section 400.602, Florida Statutes, is amended to read:

400.602 Licensure required; prohibited acts; exemptions; display, transferability of license.--

(1)(a) It is unlawful to operate or maintain a hospice without first obtaining a license from the agency.

(b) It is unlawful for any person or legal entity not licensed as a hospice under this part to use the word "hospice" in its name, or to offer or advertise hospice services or hospice-like services in such a way as to mislead a person to believe that the offeror is a hospice licensed under this part.

(c) It is unlawful for any person or legal entity offering, describing, or advertising hospice services or

hospice-like services or otherwise holding itself out as a hospice to do so without stating the year of initial licensure as a hospice in the state or the year of initial licensure of the hospice entity or affiliate based in the state that owns the hospice. At a minimum, the year of initial licensure shall be stated directly beneath the name of the licensed entity in a type no less than 25 percent of the size of the type used for the name or other indication of hospice services or hospice-like services and must be prominently stated at least one time on any document, item, or other medium offering, describing, or advertising hospice services or hospice-like services.

(2) Services provided by a hospital, nursing home, or other health care facility, health care provider, or caregiver, or under the Community Care for the Elderly Act, do not constitute a hospice unless the facility, provider, or caregiver establishes a separate and distinct administrative program to provide home, residential, and homelike inpatient hospice services.

(3)(a) A separately licensed hospice may not use a name which is substantially the same as the name of another hospice licensed under this part.

(b) A licensed hospice which intends to change its name or address must notify the agency at least 60 days before making the change.

(4) The license shall be displayed in a conspicuous place inside the hospice program office; shall be valid only in the possession of the person or public agency to which it is issued; shall not be subject to sale, assignment, or other transfer,

voluntary or involuntary; and shall not be valid for any hospice other than the hospice for which originally issued.

(5) A hospice must serve the entire service area for which it is licensed. For any county or counties in the service area with a population of 50,000 or less, the hospice must have a plan for providing hospice care, meeting the needs for hospice care, and reporting access and utilization of hospice care by county residents; must locate an office in the county; and must employ local hospice staff or trained volunteers within 6 months after initial licensure.

~~(5) Notwithstanding s. 400.601(3), any hospice operating in corporate form exclusively as a hospice, incorporated on or before July 1, 1978, may be transferred to a for profit or not for profit entity, and may transfer the license to that entity.~~

~~(6) Notwithstanding s. 400.601(3), at any time after July 1, 1995, any entity entitled to licensure under subsection (5) may obtain a license for up to two additional hospices in accordance with the other requirements of this part and upon receipt of any certificate of need that may be required under the provisions of ss. 408.031-408.045.~~

Section 3. Subsection (7) is added to section 400.606, Florida Statutes, to read:

400.606 License; application; renewal; conditional license or permit; certificate of need.--

(7) The agency shall deny a license or renewal of a license to any hospice that fails to meet any commitment for the provision of hospice care or services made in the application for a certificate of need or any condition for the provision of

hospice care or services specified in the certificate of need, unless the hospice can demonstrate that meeting a commitment or condition is premature to the initial issuance of a license.

Section 4. Subsection (4) of section 400.6105, Florida Statutes, is amended to read:

400.6105 Staffing and personnel.--

(4) A hospice must maintain a trained volunteer staff for the purpose of providing both administrative support and direct patient care. A hospice must use trained volunteers who work in defined roles and under the supervision of a designated hospice employee for an amount of time that equals at least 5 percent of the total patient care hours provided by all paid hospice employees and contract staff in the aggregate. The hospice shall document and report the use of volunteers, including maintaining a record of the number of volunteers, the number of hours worked by each volunteer, and the tasks performed by each volunteer.

Section 5. No later than January 1, 2010, the Office of Program Policy Analysis and Government Accountability shall submit to the President of the Senate and the Speaker of the House of Representatives a report analyzing the impact of for-profit hospices on the delivery of care to terminally ill patients and include in the report a review of the quality of care offered by for-profit hospices, changes in the competitive marketplace in hospice service areas, and any other information deemed pertinent.

Section 6. In order to protect the citizens of the state, it is the intent of the Legislature that no change in law or in administrative rule be made to the hospice licensure and

certificate-of-need provisions until the year 2012 in order to correctly analyze and evaluate the impact of this act on the quality of hospice care in the state.

Section 7. (1) No later than December 31, 2007, the Department of Elderly Affairs, in conjunction with the Agency for Health Care Administration and all hospices licensed in the state, shall develop outcome measures to determine the quality and effectiveness of hospice care in the state. At a minimum, these outcome measures shall include a requirement that 50 percent of patients who report severe pain on a 0-to-10 scale must report a reduction to 5 or less by the end of the 4th day of care on the hospice program.

(2) The Department of Elderly Affairs, in conjunction with the Agency for Health Care Administration and all hospices licensed in the state, shall:

(a) Consider and adopt national initiatives, such as those developed by the National Hospice and Palliative Care Organization, to set benchmarks for measuring the quality of hospice care provided in the state.

(b) Develop an annual report that analyzes and evaluates the information collected under this act and any other data collection or reporting provisions of law.

Section 8. If any provision of this act or its application to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of this act which can be given effect without the invalid provision or application, and to this end the provisions of this act are severable.

Section 9. This act shall take effect July 1, 2006.

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. (for drafter's use only)

Bill No. **1417 CS**

COUNCIL/COMMITTEE ACTION

| | |
|---|---|
| ADOPTED | __ (Y/N) |
| ADOPTED AS AMENDED | __ (Y/N) |
| ADOPTED W/O OBJECTION | __ (Y/N) |
| FAILED TO ADOPT | __ (Y/N) |
| WITHDRAWN | __ (Y/N) |
| OTHER | _____ |

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Council/Committee hearing bill: Health Care Appropriations

Representative Sansom offered the following:

**Amendment (with title amendment)**

Remove everything after the enacting clause and insert:

Section 1. Subsection (3) of section 400.601, Florida Statutes, is amended to read:

400.601 Definitions.--As used in this part, the term:

(3) "Hospice" means a centrally administered corporation ~~not for profit, as defined in chapter 617,~~ providing a continuum of palliative and supportive care for the terminally ill patient and his or her family.

Section 2. Section 400.602, Florida Statutes, is amended to read:

400.602 Licensure required; prohibited acts; exemptions; display, transferability of license.--

(1)(a) It is unlawful to operate or maintain a hospice without first obtaining a license from the agency.

(b) It is unlawful for any person or legal entity not licensed as a hospice under this part to use the word "hospice" in its name, or to offer or advertise hospice services or

hospice-like services in such a way as to mislead a person to believe that the offeror is a hospice licensed under this part.

(c) It is unlawful for any person or legal entity offering, describing, or advertising hospice services or hospice-like services or otherwise holding itself out as a hospice to do so without stating the year of initial licensure as a hospice in the state or the year of initial licensure of the hospice entity or affiliate based in the state that owns the hospice. At a minimum, the year of initial licensure must be stated directly beneath the name of the licensed entity in a type no less than 25 percent of the size of the type used for the name or other indication of hospice services or hospice-like services and must be prominently stated at least one time on any document, item, or other medium offering, describing, or advertising hospice services or hospice-like services. This excludes any materials relating to the care and treatment of an existing hospice patient.

(2) Services provided by a hospital, nursing home, or other health care facility, health care provider, or caregiver, or under the Community Care for the Elderly Act, do not constitute a hospice unless the facility, provider, or caregiver establishes a separate and distinct administrative program to provide home, residential, and homelike inpatient hospice services.

(3)(a) A separately licensed hospice may not use a name which is substantially the same as the name of another hospice licensed under this part.

(b) A licensed hospice which intends to change its name or address must notify the agency at least 60 days before making the change.

(4) The license shall be displayed in a conspicuous place inside the hospice program office; shall be valid only in the possession of the person or public agency to which it is issued; shall not be subject to sale, assignment, or other transfer, voluntary or involuntary; and shall not be valid for any hospice other than the hospice for which originally issued.

~~(5) Notwithstanding s. 400.601(3), any hospice operating in corporate form exclusively as a hospice, incorporated on or before July 1, 1978, may be transferred to a for profit or not-for-profit entity, and may transfer the license to that entity.~~

~~(6) Notwithstanding s. 400.601(3), at any time after July 1, 1995, any entity entitled to licensure under subsection (5) may obtain a license for up to two additional hospices in accordance with the other requirements of this part and upon receipt of any certificate of need that may be required under the provisions of ss. 408.031-408.045.~~

Section 3. Subsection (7) is added to section 400.606, Florida Statutes, to read:

400.606 License; application; renewal; conditional license or permit; certificate of need.--

(7) The agency may deny a license to an applicant that fails to meet any condition for the provision of hospice care or services imposed by the agency on a certificate of need by final agency action, unless the hospice can demonstrate that good cause exists for the applicant's failure to meet such condition.

Section 4. Subsection (4) of section 400.6105, Florida Statutes, is amended to read:

400.6105 Staffing and personnel.--

(4) A hospice must maintain a trained volunteer staff for the purpose of providing both administrative support and direct patient care. A hospice must use trained volunteers who work in

defined roles and under the supervision of a designated hospice employee for an amount of time that equals at least 5 percent of the total patient care or administrative hours provided by all paid hospice employees and contract staff in the aggregate. The hospice shall document and report the use of volunteers, including maintaining a record of the number of volunteers, the number of hours worked by each volunteer, and the tasks performed by each volunteer.

Section 5. No later than January 1, 2010, the Office of Program Policy Analysis and Government Accountability shall submit to the President of the Senate and the Speaker of the House of Representatives a report analyzing the impact of for-profit hospices on the delivery of care to terminally ill patients and include in the report a review of the quality of care offered by for-profit hospices, changes in the competitive marketplace in hospice service areas, and any other information deemed pertinent.

Section 6. To protect the citizens of the state, it is the intent of the Legislature that no change in law be made to the hospice licensure and certificate-of-need provisions until the year 2012 to correctly analyze and evaluate the impact of this act on the quality of hospice care in the state.

Section 7. (1) No later than December 31, 2007, the Department of Elder Affairs, in conjunction with the Agency for Health Care Administration and all hospices licensed in the state, shall develop outcome measures to determine the quality and effectiveness of hospice care in the state. At a minimum, these outcome measures shall include a requirement that 50 percent of patients who report severe pain on a 0-to-10 scale must report a reduction to 5 or less by the end of the 4th day of care on the hospice program.

(2) The Department of Elder Affairs, in conjunction with the Agency for Health Care Administration and all hospices licensed in the state, shall:

(a) Consider and adopt national initiatives, such as those developed by the National Hospice and Palliative Care Organization, to set benchmarks for measuring the quality of hospice care provided in the state.

(b) Develop an annual report that analyzes and evaluates the information collected under this act and any other data collection or reporting provisions of law.

Section 8. If any provision of this act or its application to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of this act which can be given effect without the invalid provision or application, and to this end the provisions of this act are severable.

Section 9. This act shall take effect July 1, 2006.

================= T I T L E A M E N D M E N T =================

Remove the entire title and insert:

A bill to be entitled

An act relating to hospices; amending s. 400.601, F.S.; revising the definition of the term "hospice"; amending s. 400.602, F.S.; requiring that a hospice state the year of initial licensure in the state; prescribing the manner and placement of such notification; deleting provisions authorizing the transfer of certain hospices and the acquisition of additional licenses; amending s. 400.606, F.S.; requiring the Agency for Health Care Administration to deny a license to hospices that fail to meet certain conditions; amending s. 400.6105, F.S.; requiring a

hospice to use trained volunteers and to document and report certain volunteer information; requiring the Office of Program Policy Analysis and Government Accountability to submit a report to the Legislature; providing legislative intent; providing that the Department of Elder Affairs, in conjunction with the agency and all hospices licensed in the state, develop certain outcome measures; providing for adoption of national initiatives; requiring an annual report; providing for severability; providing an effective date.

# HOUSE OF REPRESENTATIVES STAFF ANALYSIS

**BILL #:** HB 1449 CS Brain Tumor Research
**SPONSOR(S):** Gannon and others
**TIED BILLS:** HB 1451 **IDEN./SIM. BILLS:** SB 2566

| REFERENCE | ACTION | ANALYST | STAFF DIRECTOR |
|---|---|---|---|
| 1) Health Care General Committee | 10 Y, 0 N, w/CS | Ciccone | Brown-Barrios |
| 2) Health Care Appropriations Committee | | Money (CM) | Massengale SM |
| 3) Health & Families Council | | | |
| 4) | | | |
| 5) | | | |

## SUMMARY ANALYSIS

House Bill 1449 CS establishes the Florida Center for Brain Tumor Research within the Scripps Research Institute. The bill provides legislative intent regarding the need for coordination among researchers and health care providers in the effort to find cures for cancerous and noncancerous brain tumors.

The bill directs the Scripps Research Institute to work with the University of Florida McKnight Brain Institute to develop and maintain an automated centralized database of individuals with brain tumors. The bill creates the Florida Center for Brain Tumor Research within the Scripps Research Institute and directs the center to provide a central repository for brain tumor biopsies. In addition, the center is directed to improve and monitor brain tumor biomedical research programs, facilitate funding opportunities, and foster improved technology transfer of brain tumor research findings into clinical trials and public use.

The bill creates a scientific advisory council within the Florida Center for Brain Tumor Research membership includes biomedical researchers, physicians, clinicians, and representatives from public and private universities and hospitals; members of the council serve without compensation.

The bill has a $4 million fiscal impact. Funds would be appropriated from the General Revenue Fund to the Florida Center for Brain Tumor Research for the 2006-2007 fiscal year for the purpose of funding brain tumor research and the procurement of brain tumor biopsies. The bill specifies that up to 10 percent of the total funds appropriated to be used for administrative costs.

The effective date of the bill is July 1, 2006.

## FULL ANALYSIS

## I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

**Provide limited government**—The bill expands the duties and responsibilities of the Department of Health to develop and maintain an automated, electronic, and centralized brain tumor registry.

**Empower families**—Individuals in need of information and treatment of cancerous and noncancerous brain tumors would benefit from the advances in information and technology as biomedical research extends to expand clinical research trials and eventual cures.

B. EFFECT OF PROPOSED CHANGES:

Current sections of law delineate a growing emphasis to encourage biomedical and clinical trial research in a variety of tumor-related areas of study in Florida. Several universities, including the University of Florida, University of Miami and the University of South Florida have well established programs dealing with cancerous and noncancerous brain tumor research. In addition, the H. Lee Moffitt Cancer Center and Research Institute and the Florida Hospital in Orlando are listed in the national registry of brain tumor centers. Publicly and privately funded research consortiums such as the Scripps Research Institute provide a continuum of innovative research opportunities to foster communication and coordination among researchers and institutions, increase federal and other grant opportunities and expand the related economic industry growth.

**Background**

Tumors – General Definition

A tumor or neoplasm refers to a "new growth" of cells that already exist in a certain part of the body. Many different tumors can occur in the nervous system. They often cause headaches, seizures or neurological deficits. Tumors can be either benign or malignant. Malignant tumors are referred to as cancers. Tumor treatments can consist of surgical resection or biopsy, radiation approaches or drug treatment approaches (chemotherapy). Other tumors can be treated with modification of the body's own immune system (immunotherapy).[1]

There are many types of brain tumor disorders including acoustic neuroma, astrocytoma, brain metastasis, and glioblastoma. Because of the many and varied types of brain tumors, treatment is complicated. Brain tumors in children are different from those in adults and are often treated differently. Although as many as 60 percent of children will survive, they are often left with long term side effects. In addition, brain tumors are the third leading cause of death in young adults ages 20—39.[2]

The American Cancer Society estimates that 18,820 Americans have been diagnosed with malignant brain or spinal cord tumors in 2005 and that 12,820 of these patients will die from these malignant tumors; 930 of these deaths that occurred in 2005 were in Florida.

The National Brain Tumor Foundation reports the following statistics:

- Each year approximately 190,000 people in the United States will be diagnosed with a primary or metastatic brain tumor.

[1] *See Department of Neurological Surgery, University of Pittsburg, www.neurosurgery.pitt.edu/conditions*
[2] National Brain Tumor Foundation website www.braintumor.org/patient/treatment

- Brain tumors are the leading cause of Solid Tumor death in children under age 20 now surpassing acute lymphoblastic leukemia (ALL), and are the third leading cause of cancer death in young adults ages 20-39.
- Brain tumor patients, including those with certain "benign" brain tumors, have poorer survival rates than breast cancer patients.
- Metastatic brain tumors (cancer that spreads from other parts of the body to the brain) occur at some point in 10 to 15 percent of persons with cancer and are the most common type of brain tumor. The incidence of brain tumors has been increasing as cancer patients live longer.
- In the United States, the overall incidence of all primary brain tumors is more than 14 per 100,000 people.
- Because brain tumors are located at the control center for thought, emotion and movement, their effects on an individual's physical and cognitive abilities can be devastating.
- Brain tumors are treated by surgery, radiation therapy and chemotherapy, used either individually or in combination.
- Only 31 percent of males and 30 percent of females survive five years following the diagnosis of a primary or malignant brain tumor.
- Brain tumors in children are different from those in adults and are often treated differently. Although as many as 69 percent of children with brain tumors will survive, they are often left with long-term side effects.
- Enhancing the quality of life of people with brain tumors requires access to quality specialty care, clinical trials, follow-up care and rehabilitative services. Improving the outlook for adults and children with brain tumors requires research into the causes of and better treatments of brain tumors.
- Complete and accurate data on all primary brain tumors are needed to provide the foundation for research leading to improved diagnosis and treatment and to investigations of its causes.

BRAIN TUMOR SYMPTONS AND TREATMENT

Symptoms of a brain tumor can include headaches (of sufficient discomfort to disrupt sleep), seizures in a person who does not have a history of seizures, cognitive or personality changes, eye weakness, nausea or vomiting, speech disturbances, or memory loss. While these are the most common symptoms of a brain tumor, they can also indicate other medical problems.

At present, surgery is the primary treatment for brain tumors that lie within those membranes covering the brain or in parts of the brain that can be removed without damaging critical neurogical functions. Because a tumor can regrow if any tumor cells are left behind, surgeons strive to remove the entire tumor whenever possible. Radiation therapy and chemotherapy, in general are used as secondary or adjuvant treatment for tumors that cannot be removed by surgery alone.

C. SECTION DIRECTORY:

**Section 1.** Creates section 381.853, F.S., and provides legislative intent regarding cancerous and noncancerous biomedical research; directing the Scripps Research Institute to work with the University of Florida McKnight Brain Institute to develop and maintain a centralized database of brain tumor information; creating the Florida Center for Brain Tumor Research within the Scripps Research Institute; and creating a scientific advisory council.

**Section 2.** Provides a $4 million appropriation from the General Revenue Fund to the Florida Center for Brain Tumor Research for the 2006-2007 fiscal year.

**Section 3.** Provides an effective date of July 1, 2006.

## II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None

2. Expenditures:

According to the Department of Health, the department will need additional funding to develop a specific automated, electronic and centralized database of individuals with brain tumors and to provide staffing necessary to maintain quality, completeness and timeliness of the registry data; develop and maintain rules; and to participate in the Advisory Council meetings and activities.

| Estimated Expenditures | 1st Year | 2nd Year (Annualized/Recurring) |
|---|---|---|
| Salaries | | |
| 2 OMC II @$38,048 | $ 76,096 | $ 77,997 |
| 1 OMC Mgr. @$42,818 | $ 42,818 | $ 43,889 |
| 29% fringe | $ 34,485 | $ 35,347 |
| Total | $153,399 | $157,233 |
| Expense | | |
| 3 FTE @ Standard Professional Expense Package with Medium Travel $16,460 1st year - $13,117 Recurring | $ 49,380 | $ 39,351 |
| Operating Capital Outlay | | |
| 3 FTE @ Standard OCO $1,900 1st year | $ 5,700 | $ - 0 – |
| Total Estimates Expenditures | $208,479 | $196,584 |

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None

2. Expenditures:

None

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None

D. FISCAL COMMENTS:

See Fiscal Note above.

## III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   This bill does not require counties or municipalities to take an action requiring the expenditure of funds, nor does it reduce the authority that counties or municipalities have to raise revenue in the aggregate, nor does it reduce the percentage of state tax shared with counties or municipalities.

2. Other:

   None

B. RULE-MAKING AUTHORITY:

The bill provides rule making authority for the Department of Health to implement the provisions of this bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

## IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

On March 28, 2006, the House Health Care General Committee passed House Bill 1449 CS and adopted one strike-all amendment that made the following changes:

- Directed the Scripps Research Institute to work with the University of Florida McKnight Brain Institute to maintain a brain tumor registry.
- Established the Florida Center for Brain Tumor Research within the Scripps Research Institute.
- Provided for the brain tumor biomedical technology summit to include scientists conducting basic peer-reviewed scientific research.
- Specified that the center shall include clinicians among researchers, physicians and hospitals fostering partnerships, information sharing and membership in the scientific advisory council.
- Provided annual reporting requirements.
- Specified up to 10 percent of the $4 million appropriation to the Florida Center for Brain Tumor Research may be used for administrative costs.

The analysis is drafted to the bill as amended.

CHAMBER ACTION

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The Health Care General Committee recommends the following:

**Council/Committee Substitute**

Remove the entire bill and insert:

A bill to be entitled

An act relating to brain tumor research; creating s. 381.853, F.S.; providing legislative findings and intent; requiring the Scripps Research Institute to work with the University of Florida McKnight Brain Institute to develop and maintain a brain tumor registry; providing that individuals may choose not to be listed in the registry; establishing the Florida Center for Brain Tumor Research within the Scripps Research Institute; providing purpose and goal of the center; requiring certain funds for brain tumor research to be awarded on a competitive basis; requiring the center to hold an annual brain tumor biomedical technology summit; providing for clinical trials and collaboration between certain entities; requiring the center to submit an annual report to the Governor, Legislature, and Secretary of Health; providing for funding; establishing a scientific advisory council and providing for composition and terms thereof; providing

rulemaking authority to the department; providing an appropriation; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 381.853, Florida Statutes, is created to read:

381.853 Florida Center for Brain Tumor Research.--

(1) The Legislature finds that each year an estimated 190,000 citizens of the United States are diagnosed with cancerous and noncancerous brain tumors and that biomedical research is the key to finding cures for these tumors. The Legislature further finds that, although brain tumor research is being conducted throughout the state, there is a lack of coordinated efforts among researchers and health care providers. Therefore, the Legislature finds that there is a significant need for a coordinated effort to achieve the goal of curing brain tumors. The Legislature further finds that the biomedical technology sector meets the criteria of a high-impact sector, pursuant to s. 288.108(6), having a high importance to the state's economy with a significant potential for growth and contribution to our universities and quality of life.

(2) It is the intent of the Legislature to establish a coordinated effort among the state's public and private universities and hospitals and the biomedical industry to discover brain tumor cures and develop brain tumor treatment modalities. Moreover, it is the intent of the Legislature to

expand the state's economy by attracting biomedical researchers and research companies to the state.

(3) The Scripps Research Institute shall work with the University of Florida McKnight Brain Institute to develop and maintain a brain tumor registry that is an automated, electronic, and centralized database of individuals with brain tumors. The individual, or the parent or guardian of the individual if the individual is a minor, may refuse to participate in the brain tumor registry by signing a form obtained from the Department of Health or from the health care practitioner or entity that provides brain tumor care or treatment, which indicates that the individual does not wish to be included in the registry. The decision to not participate in the registry must be noted in the registry.

(4) There is established within the Scripps Research Institute the Florida Center for Brain Tumor Research.

(a) The purpose of the center is to provide a central repository for brain tumor biopsies from individuals throughout the state, improve and monitor brain tumor biomedical research programs within the state, facilitate funding opportunities, and foster improved technology transfer of brain tumor research findings into clinical trials and widespread public use.

(b) The goal of the center is to find cures for brain tumors.

(c) Funds specifically appropriated by the Legislature for peer-reviewed brain tumor research shall be awarded on a competitive basis by means of a grant process developed by the center.

(d) The center shall hold an annual brain tumor biomedical technology summit in the state to which scientists conducting basic peer-reviewed scientific research from the state's public and private universities, teaching hospitals, and for-profit and nonprofit institutions are invited to share biomedical research findings in order to expedite the discovery of cures. Summit attendees shall cover the costs of such attendance or obtain sponsorship for such attendance.

(e) The center shall encourage clinical trials in the state on research that holds the promise of curing brain tumors. The center shall facilitate partnerships between researchers, physicians, clinicians, and hospitals for the purpose of sharing new techniques and new research findings, as well as coordinating the voluntary donation of brain tumor biopsies.

(f) The center shall facilitate the formation of partnerships between researchers, physicians, clinicians, and hospitals in the state.

(g) The center shall submit an annual report to the Governor, the President of the Senate, the Speaker of the House of Representatives, and the Secretary of Health no later than January 15 that contains recommendations for legislative changes necessary to foster a positive climate for the pursuit of brain tumor research and the development of treatment modalities in the state.

(h) The center shall be funded through private, state, and federal sources.

(5) There is established within the center a scientific advisory council that includes biomedical researchers,

physicians, clinicians, and representatives from public and private universities and hospitals. The council shall meet at least annually.

(a) The council shall consist of:

1. Two members from the University of Florida McKnight Brain Institute, appointed by the Governor.

2. Two members from the Scripps Research Institute, one of whom must have expertise in basic brain tumor research, appointed by the Speaker of the House of Representatives.

3. Two members from other public and private state universities and institutions directly involved in brain tumor research, appointed by the President of the Senate.

4. Two physicians directly involved in the treatment of brain tumor patients, appointed by the Secretary of Health.

(b) Council members shall serve staggered 4-year terms.

(c) Council members shall serve without compensation, and each organization represented shall cover all expenses of its representative.

(6) The Department of Health may adopt, repeal, and amend rules pursuant to ss. 120.536(1) and 120.54 relating to the center and the administration of the brain tumor registry. Such rules may include procedures for participating in brain tumor research and for providing access to confidential information necessary for brain tumor investigations. For the purposes of the brain tumor registry, the rules may include procedures for a health care practitioner and researcher to obtain authorization to use the brain tumor registry and methods for an individual or

guardian to elect not to participate in the brain tumor registry.

Section 2. The sum of $4 million is appropriated from the General Revenue Fund to the Florida Center for Brain Tumor Research for the 2006-2007 fiscal year for the purpose of funding brain tumor research and funding for the procurement of brain tumor biopsies. From the total funds appropriated, an amount of up to 10 percent may be used for administrative costs.

Section 3. This act shall take effect July 1, 2006.

HOUSE AMENDMENT FOR COUNCIL/COMMITTEE PURPOSES

Amendment No. 01(for drafter's use only)

Bill No. **1449 CS**

COUNCIL/COMMITTEE ACTION

| | |
|---|---|
| ADOPTED | __ (Y/N) |
| ADOPTED AS AMENDED | __ (Y/N) |
| ADOPTED W/O OBJECTION | __ (Y/N) |
| FAILED TO ADOPT | __ (Y/N) |
| WITHDRAWN | __ (Y/N) |
| OTHER | _____ |

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Council/Committee hearing bill: Health Care Appropriations

Representative Gannon offered the following:

**Amendment (with title amendment)**

Remove everything after the enacting clause and insert:

Section 1. Section 381.853, Florida Statutes, is created to read:

381.853 Florida Center for Brain Tumor Research.--

(1) The Legislature finds that each year an estimated 190,000 citizens of the United States are diagnosed with cancerous and noncancerous brain tumors and that biomedical research is the key to finding cures for these tumors. The Legislature further finds that, although brain tumor research is being conducted throughout the state, there is a lack of coordinated efforts among researchers and health care providers. Therefore, the Legislature finds that there is a significant need for a coordinated effort to achieve the goal of curing brain tumors. The Legislature further finds that the biomedical technology sector meets the criteria of a high-impact sector, pursuant to s. 288.108(6), having a high importance to the state's economy with a significant potential for growth and contribution to our universities and quality of life.

(2) It is the intent of the Legislature to establish a coordinated effort among the state's public and private universities and hospitals and the biomedical industry to discover brain tumor cures and develop brain tumor treatment modalities. Moreover, it is the intent of the Legislature to expand the state's economy by attracting biomedical researchers and research companies to the state.

(3) The University of Florida McKnight Brain Institute shall work with other institutions and organizations to develop and maintain a brain tumor registry that is an automated, electronic, and centralized database of individuals with brain tumors. The individual, or the parent or guardian of the individual if the individual is a minor, may refuse to participate in the brain tumor registry by signing a form obtained from the department or from the health care practitioner or entity that provides brain tumor care or treatment, which indicates that the individual does not wish to be included in the registry. The decision to not participate in the registry must be noted in the registry.

(4) The Florida Center for Brain Tumor Research is established within the Evelyn F. and William L. McKnight Brain Institute of the University of Florida.

(a) The purpose of the center is to foster collaboration with brain cancer research organizations and other institutions, provide a central repository for brain tumor biopsies from individuals throughout the state, improve and monitor brain tumor biomedical research programs within the state, facilitate funding opportunities, and foster improved technology transfer of brain tumor research findings into clinical trials and widespread public use.

(b) The goal of the center is to find cures for brain tumors.

(c) Funds specifically appropriated by the Legislature for peer reviewed brain tumor research shall be awarded on a competitive grant process developed by the Florida Brain Tumor Research Center.

(d) The center shall hold an annual brain tumor biomedical technology summit in the state to which scientists conducting basic peer reviewed scientific research from the state's public and private universities, teaching hospitals, and from for-profit and non-profit institutions are invited to share biomedical research findings in order to expedite the discovery of cures. Summit attendees shall cover the costs of such attendance or obtain sponsorship for such attendance.

(e) The center shall encourage clinical trials in the state on research that holds the promise of curing brain tumors. The center shall facilitate partnerships between researchers, physicians, clinicians and hospitals for the purpose of sharing new techniques and new research findings, as well as coordinating the voluntary donation of brain tumor biopsies.

(f) The center shall facilitate the formation of partnerships between researchers, physicians, clinicians and hospitals in the state.

(g) The center shall submit an annual report to the Governor, the President of the Senate, the Speaker of the House of Representatives, and the Secretary of the Department of Health no later than January 15$^{th}$ which contains recommendations for legislative change necessary to foster a positive climate for brain tumor research and treatment modalities in this state.

(h) The center shall be funded through private, state, and federal sources.

(5) There is established within the center a scientific advisory council that includes biomedical researchers, physicians, clinicians and representatives from public and private universities and hospitals. The council shall meet at least annually.

(a) The council shall consist of:

1. Two members from the Florida McKnight Brain Institute Center for Brain Therapy appointed by the Governor.

2. Two members from the Scripps Institute, one with an expertise in basic brain tumor research, appointed by the Speaker of the House.

3. Two members from other public and private state universities and institutions directly involved in brain tumor research, appointed by the President of the Senate.

4. Two physicians directly involved in the treatment of brain tumor patients appointed by the Secretary of the Department of Health.

(b) Council members shall serve staggered 4-year terms.

(c) Members of the council shall serve without compensation, and each organization represented shall cover all expenses of its representative.

Section 2. The sum of $500,000 is appropriated from the General Revenue Fund to the Evelyn F. and William L. McKnight Brain Institute of the University of Florida for the 2006-2007 fiscal year. The level of funding for brain tumor research and the procurement of brain tumor biopsies shall be commensurate with the level of funding provided.

Section 3. This act shall take effect July 1, 2006.

========== T I T L E A M E N D M E N T ==========

Remove the entire title and insert:

Amendment No. 01(for drafter's use only)

A bill to be entitled

An act relating to brain tumor research; creating s. 381.853, F.S.; providing legislative findings and intent; requiring the Evelyn F. and William L. McKnight Brain Institute of the University of Florida to develop and maintain a brain tumor registry; providing that individuals may choose not to be listed in the registry; establishing the Florida Center for Brain Tumor Research within the Evelyn F. and William L. McKnight Brain Institute of the University of Florida; providing purpose and goal of the center; requiring the center to hold an annual brain tumor biomedical technology summit; providing for clinical trials and collaboration between certain entities; providing for funding; establishing a scientific advisory council and providing for composition and terms thereof; providing an appropriation; providing an effective date.